FoodSafety magazine

FEBRUARY/MARCH 2023

Why a Paradigm Shift Is Needed In Food Safety Auditing

Looking Back: *E. coli* O157:H7 and the Legacy of Dr. David Theno

Reducing Food Safety Risks in Meal Kits

Pre-Harvest Strategies to Reduce Pathogens in Red Meat

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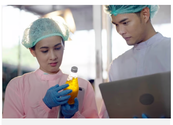

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FDA *Food Code*, Age 30, Up for Adoption (in New Edition)

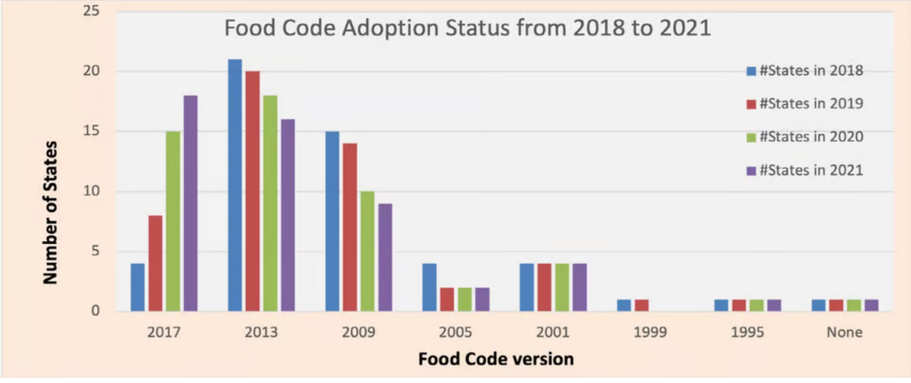
The U.S. Food and Drug Administration (FDA) *Food Code*, which is based on recommendations from the Conference for Food Protection (CFP), is a model code that represents FDA's best guidance for a uniform system of provisions for retail foodservice operations to help ensure that food is sourced, prepared, stored, presented, and served in a safe manner. It is not federal law. However, it provides scientifically sound food safety advice to more than 3,000 local, state, tribal, and federal food control agencies. California, which has adopted its own code, does not follow the FDA *Food Code*.

The *Food Code* is typically updated every four years, with supplements issued between updates, as needed. The last full update was issued in 2017. On December 28, 2022, FDA released the 2022 *Food Code* (tenth edition) to reflect the input of regulators, industry, academia, and consumers that participated in the 2020 biennial meeting of the CFP. The meeting was held in 2021 due to the pandemic, thus impacting the *Food Code* publication schedule. The tenth edition of the food code also commemorates 30 years of the *Food Code* in its current format. We will be speaking with FDA on our *Food Safety Matters* podcast about the new edition of the *Food Code* and its use over the past 30 years. So stay tuned for that upcoming episode!

Notable changes in the 2022 *Food Code* include the addition of sesame as the ninth major allergen to reflect the Food Allergy Safety, Treatment, Education, and Research Act (FASTER Act) of 2021, as well as the addition of labeling and consumer information for major allergens for unpackaged and self-dispensed food items. The 2022 *Food Code* also revises the definition of intact meat to include meats that are vacuum tumbled with solutions, making FDA's definition consistent with the U.S. Department of Agriculture's mechanically tenderized beef rule of 2015. It also clarifies time and temperature cooking requirements for these meats. Additionally, the 2022 edition creates new requirements for the allowance of pet dogs in outdoor dining spaces, and addresses safe protocols for food intended to be used as food donations. It also lowers the required water temperature at handwashing sinks from at least 100 °F, or 38 °C, to at least 85 °F, or 29.4 °C, and clarifies the naming conventions for several food types. Finally, restricted-use pesticides are now defined as poisonous or toxic materials in the 2022 *Food Code*.

FDA's *Food Code* has been adopted by 49 states (with the exception of California, as previously stated) in some form. As of the end of 2021, 18 states were using the 2017 version, and 16 states were using the 2013 version. Fifteen other states plus the District of Columbia were using *Food Code* versions from 2009 or older. The bureaucratic structure of agencies responsible for regulatory oversight over retail and foodservice establishments varies in each state, which means that the number of state agencies (typically one to three) that have the ability to adopt the *Food Code* as policy can vary significantly. This is one reason for the difference in the speed of adoption of *Food Code* editions among states (Figure 1[1]).

FIGURE 1. *Food Code* Adoption Status among States, 2018–2021 (Source: FDA[1])



It is hoped that the release of the 2022 edition will bring more states on board with the updated version, as it is difficult to maintain consistent food safety standards in retail foodservice operations when so much variance exists in adherence to code across states. The desire to get more states on board with the updated version of the *Food Code* may be one reason that FDA is increasing its focus on retail food safety.

At our 2023 Food Safety Summit in May, we will also increase our focus on retail foodservice with separate foodservice and retail/e-commerce/convenience store community group discussions on the morning of Wednesday, May 10. On Wednesday afternoon, an education session will examine the regulatory impacts of the 1993 Jack in the Box *E. coli* outbreak, including the creation of the *Food Code* and HACCP. The Summit will also devote an entire education session to food safety practices in the real world, with discussion of a survey developed by the Association of Food and Drug Officials (AFDO) and the Retail Food Safety Regulatory Association Collaborative on the afternoon of Thursday, May 11. An additional session on Thursday afternoon will examine sanitary design in retail and restaurant facilities. Also, in line with recent adjustments made in the 2022 *Food Code*, another Thursday session will examine how to reduce food loss and waste through food donations and other initiatives.

I encourage you to take a look at the 2023 Food Safety Summit agenda and pick out your "must attend" sessions (and register) today!

Regards,

Adrienne Blume,
Editorial Director

References

1. U.S. Food and Drug Administration. "Adoption of the FDA *Food Code* by State and Territorial Agencies Responsible for the Oversight of Restaurants and/or Retail Food Stores." 2021. https://www.fda.gov/media/107543/download.

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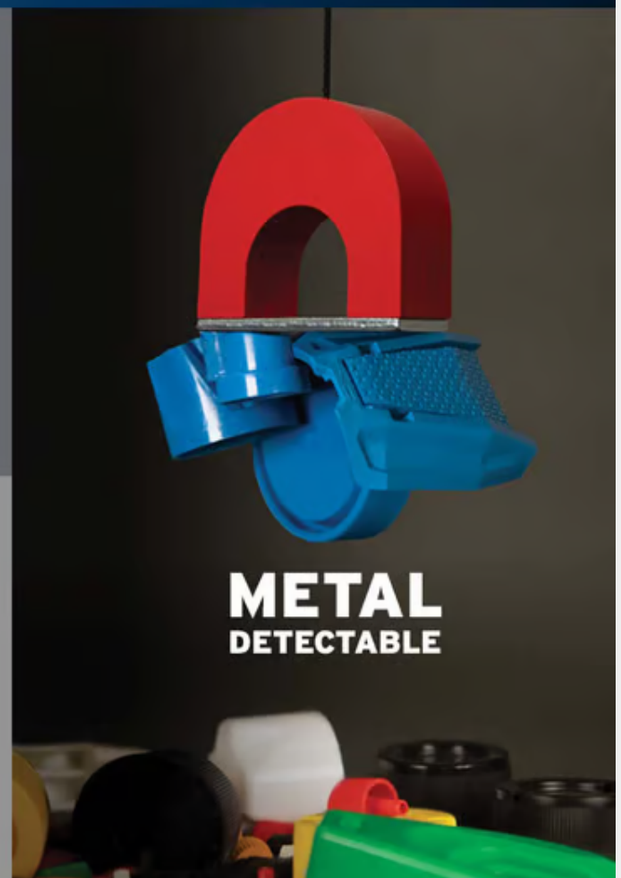
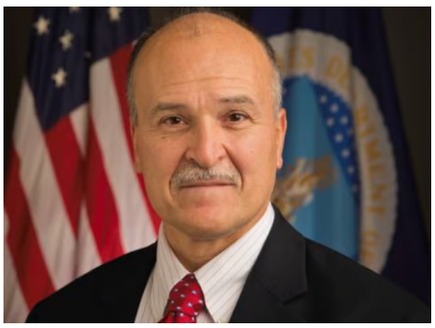


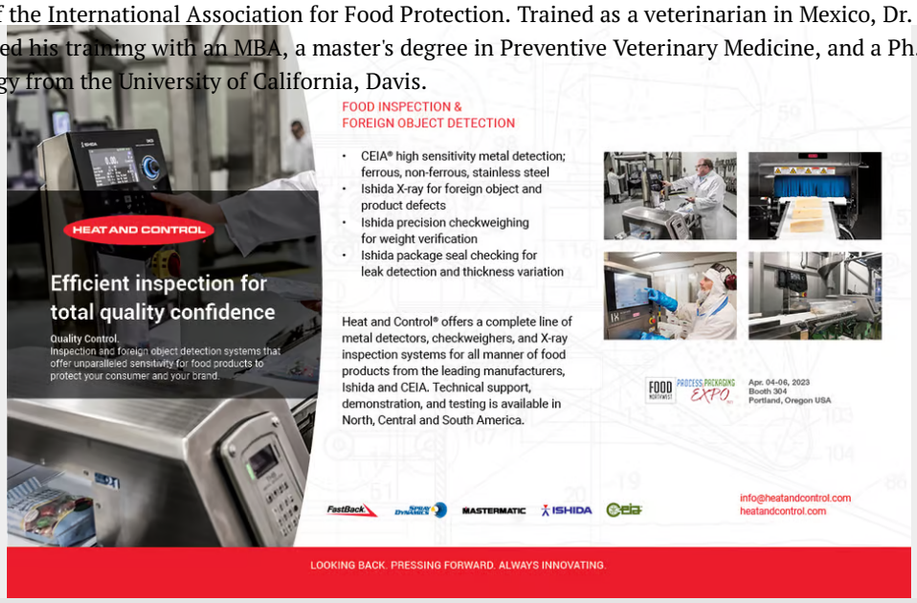


Senate Confirms Esteban as USDA Under Secretary for Food Safety

On December 23, 2022, the Senate voted to confirm Dr. Jose Emilio Esteban as the U.S. Department of Agriculture's (USDA's) sixth Under Secretary for Food Safety. The action came on the last day before the 177th Congress expired. President Biden nominated Esteban as the nation's sixth Under Secretary for Food Safety at USDA on November 15, 2021. The Senate Committee on Agriculture, Nutrition, and Forestry was tasked with reviewing the nomination, but it did not give Esteban a hearing until September 27, 2022. The office remained vacant while waiting for the Senate to act.

Dr. Esteban started his tenure at USDA's Food Safety and Inspection Service (FSIS) in 2001 and held the roles of laboratory director for the Western Laboratory, scientific advisor for laboratory services and research coordination, and executive associate for laboratory services. In 2018, he was appointed chief scientist of FSIS. In his role, Dr. Esteban provides scientific advice to support agency policies including the disciplines of microbiology, chemistry, and pathology. Prior to joining USDA, Dr. Esteban worked at the U.S. Centers for Disease Control and Prevention (CDC) as an epidemic intelligence service officer, staff epidemiologist, and assistant director of the Food Safety Office.

He currently serves as the chair for the *Codex Alimentarius* Commission Committee on Food Hygiene, the committee where international food hygiene standards are defined for international trade. He is also currently vice president of the International Association for Food Protection. Trained as a veterinarian in Mexico, Dr. Esteban supplemented his training with an MBA, a master's degree in Preventive Veterinary Medicine, and a Ph.D. in Epidemiology from the University of California, Davis.



U.S. FOOD & DRUG ADMINISTRATION

FDA Issues FSMA Food Traceability Final Rule

On November 15, 2022, the U.S. Food and Drug Administration (FDA) issued its final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) under the Food Safety Modernization Act (FSMA) Section 204(d). The Food Traceability Final Rule is designed to facilitate faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and associated deaths.

The compliance date for all operations subject to the recordkeeping requirements of the Food Traceability Final Rule is January 20, 2026. FDA clarified that no records will be requested prior to the compliance date, and that the agency will engage in stakeholder outreach, technical support, and education prior to and after January 20, 2026. FDA will provide similar support and translations of the final rule and relevant communications for foreign trading partners, as well.

Foods subject to the final rule requirements appear on the Food Traceability List (FTL). The FTL includes fresh-cut fruits and vegetables, shell eggs, and nut butters, as well as certain fresh fruits, fresh vegetables, ready-to-eat (RTE) deli salads, cheeses, and seafood products. FDA clarified that frozen foods are not included on the FTL; however, ingredients used in final food products will be subject to the final rule if the ingredients remain in the form specified on the FTL.

At the core of the final rule is a requirement that individuals who manufacture, process, pack, or hold food on the FTL maintain records including Key Data Elements (KDEs) related to Critical Tracking Events (CTEs). When requested by FDA, covered firms and farms, retail food establishments, and restaurants will be required to provide information to the agency within 24 hours, or another reasonable time to which FDA agrees. Records may be requested in the event of food safety incidents, and records for individual establishments may be kept offsite as long as they are able to be produced onsite within 24 hours.

The final rule provides full and partial exemptions for some entities and foods, such as certain small producers, small retail food establishments and restaurants, farms that sell food directly to consumers, foods that receive certain types of processing, and other specified operations. The final rule aligns with current industry best lishments, restaurants, and farms, as well as foreign firms

Reagan-Udall Review Guides "New Vision" for FDA Human Foods Program

The Reagan-Udall Foundation has published its independent review of FDA's Human Foods Program, highlighting key findings and providing recommendations regarding organizational culture, structure, resources, and authorities. The evaluation will be used to "inform a new vision for the FDA Human Foods Program," according to FDA Commissioner Robert M. Califf, M.D., M.A.C.C. Dr. Califf suggested that FDA's "new vision" might include restructuring the existing Human Foods Program and its leadership, identifying new sources of funding, advancing the agency's critical inspectional activities, and upgrading digital technology systems.

In July 2022, Dr. Califf commissioned the Reagan-Udall Foundation to convene an independent expert panel to assess the agency's Human Foods Program, which includes the Office of Food Policy and Response (OFPR), the Center for Food Safety and Applied Nutrition (CFSAN), and relevant parts of the Office of Regulatory Affairs (ORA). The aim of the evaluation was to strengthen FDA's food regulatory role. The review was commissioned following pressing food safety and security challenges that arose during 2022, such as the infant formula safety and supply crises.

Culture

The Reagan-Udall Foundation expert panel considered input from internal and external stakeholders, including FDA staff, to review the culture of the Human Foods Program. The panel found that, despite the dedication of staff members, the culture of the Human Foods Program inhibits the agency's ability to effectively protect public health. The report points to the Human Foods Program's lack of clear vision and mission, disparate structure and consensus governance model, and the lack of a strong leader and ultimate authority. In particular, the lack of a clear, overarching leader for the Human Foods Program has contributed to a culture of indecisiveness. Additionally, the absence of a unifying mission and definition for the Human Foods Program has led to a fragmented staff, overlapping roles, competing priorities, and a lack of communication that result in what is perceived as "constant turmoil," according to the report.

The report also underlines the fact that the Human Foods Program's reliance on consensus has significant drawbacks for making decisions about taking regulatory action, and that the program must shift its culture of risk aversion to one that embraces well-informed risk-taking. Furthermore, a culture of cooperation and accountability in the Human Foods Program's field operations needs to be reestablished.

Structure

Regarding organizational structure of FDA's Human Foods Program, the expert panel found that there is no clear leader or decision-maker, outside of the Commissioner. Although the missions of CFSAN and OFPR have differences on paper, staff are often left wondering which program is responsible for decision-making. A Human Foods Program Governance Board was established in 2014 to facilitate coordinated decision-making, but it has not effectively addressed structural challenges.

Particularly problematic is the fact that ORA's implementation of policies and field work is largely independent of CFSAN, the organization that is responsible for developing and writing the policies that are then discharged with a majority of ORA's funding. Additionally, CFSAN's dual focus on food safety and nutrition—in addition to its dietary supplements and cosmetics charges—results in the center's nutrition-related responsibilities receiving lesser priority.

Resources

The expert panel agreed that the Human Foods Program is "significantly under-resourced" and in urgent need of additional personnel, financial, and information technology (IT) resources to effectively execute its duties. Funding and staffing for the Human Foods Program has grown insufficiently and at a slower pace than almost all other components of FDA. The report exemplifies CFSAN, the budget for which has remained relatively flat for more than a decade; in comparison, funding for the Human Drugs Program increased 121 percent over the same period.

Additionally, the Human Foods Program does not fully utilize its industry fee authorities provided by the Food Safety Modernization Act (FSMA) to augment its budget. FDA user fee programs account for 46 percent of the agency's overall budget, but only 1 percent of the budget for the Human Foods Program. In comparison, FDA's tobacco and human drugs activities are 100 percent and 66 percent funded by their industry user fee programs, respectively.

The Human Foods Program's insufficient budget has led to difficulties with staffing, which has also remained relatively flat since 1978, despite growing responsibilities for CFSAN under FSMA. Finally, the lack of an overarching plan and adequate resources has led to the inability for FDA to optimize IT systems. Inadequate financial, personnel, and IT resources have impeded the Human Foods Program's implementation of FSMA, as well as nutrition labeling, food additive, and Generally Recognized as Safe (GRAS) designation reviews.

Authorities

In light of FDA's increasing responsibility for food safety standard-setting and oversight, the expert panel identified areas in which it is urgent for the agency to be bolder in exercising its authorities, specifically: collecting user fees, GRAS designation, data-sharing, mandatory recall, and nutrition labeling. Finally, the expert panel proposed a list of potential new FDA authorities that would strengthen the Human Foods Program.

A New Vision

Based on the independent external review by Reagan-Udall and a separate internal review of the agency's infant

FDA Prevention Strategy to Enhance Infant Formula Safety Supports Elevating *Cronobacter* to Nationally Notifiable Disease

FDA has released an outline of a prevention strategy that is under development to prevent *Cronobacter sakazakii* contamination of powdered infant formula. The prevention strategy is being developed in response to the prolific recall of Abbott Nutrition powdered infant formula that occurred in February 2022. The formula in question was recalled after FDA investigators found insanitary conditions in Abbott Nutrition's Sturgis, Michigan manufacturing facility, which possibly contributed to *Cronobacter sakazakii* infections in four infants.

The recall added further pressure to an already stressed supply chain, resulting in a shortage that made it difficult for caregivers of infants to find certain powdered infant formula products throughout 2022. While the supply of infant formula products has been steadily increasing and FDA continues to work with manufacturers to maximize production and fill store shelves, the present strategy will outline the agency's path toward enhancing the safety of powdered infant formula products. Additionally, FDA was mandated by the U.S. Senate in June 2022 to take actions to better ensure the safety of the U.S. infant formula supply.

Actions highlighted in the prevention strategy outline include:

- Collaboration with stakeholders to better understand best practices in the manufacturing of powdered infant formula and what could be done to enhance safety
- Strengthening regulatory activities and current systems for effective oversight of powdered infant formula, including reviewing and updating the Infant Formula Compliance Program, as needed, to reflect current science on *Cronobacter* and ensure that investigators and compliance officers are equipped with the tools and resources required to enable a consistent and comprehensive approach to inspections of infant formula manufacturing facilities and compliance activities
- Reviewing and updating current guidance and rules applicable to the production of powdered infant formula, as appropriate
- Evaluating current testing requirements and determining whether improvements might be appropriate to enhance the safety of finished product

- Continual development and improvement of communications for consumers about safe formula preparation and storage
- Working with federal, state, and local partners to strengthen the ability of public health officials and firms to identify and investigate illnesses of all species of *Cronobacter*, including increased genomic surveillance and supporting the elevation of *Cronobacter sakazakii* infection among infants as a nationally notifiable disease
- Conducting and supporting research to fill knowledge gaps in the scientific understanding of *Cronobacter*, such as through collaboration with the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

The powdered infant formula prevention strategy is the third prevention strategy released by the agency, following those for bulb onions and imported enoki and wood ear mushrooms. FDA and industry representatives strategies on a recent episode of the *Food Safety Matters*

Guidance on Food Safety Best Practices for Food Delivery Businesses

FDA has highlighted a voluntary guidance document on food safety best practices for direct-to-consumer and third-party food delivery services. The guidance features several updates from the original draft, such as recommended practices for transportation directly to a consumer of perishable products, to include proper packaging; temperature control during shipping, receiving, and storage; return of compromised and abused products; and other food safety related topics.

The primary intent of the document is to provide best practices for preventing the biological, physical, and chemical contamination of foods, as well as the growth of harmful bacteria and the formation of toxins within food being transported. Specifically, the guidance includes parameters relevant to:

- Preventive controls
- Mechanisms to assess risk
- Validation and verification practices
- Recommendations for proper packaging
- Temperature control
- Receiving and storage
- Physical and chemical contamination control
- Allergen control
- General food safety information
- Suggestions for the return of compromised and abused products.

The guidance is not intended to provide a one-size-fits-all approach; rather, it aims to review some of the essential parameters that any company should consider in providing safe foods to consumers. Companies are encouraged to research, understand, and test the methods best suited to their specific operations. The guidance was prepared by the 2018–2020 Conference for Food Protection (CFP) Direct-to-Consumer Delivery Committee, and the document's presentation at CFP was postponed to 2021 due to the COVID-19 Pandemic.

EU Sets Limits for PFAS in Certain Foods

The European Commission has established maximum levels for per- and polyfluoroalkyl substances (PFAS) in certain foods. The change went into effect January 1, 2023, after which date companies may not sell foods that exceed the maximum levels for PFAS. Foods that were lawfully placed on the market before January 1, 2023 were allowed to remain on the market until their date of minimum durability or use-by date.

The maximum levels are laid out in Regulation (EC) 2022/2388, amending Regulation (EC) 1881/2006. The regulation specifically focuses on limits for perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS), which are types of PFAS that are or have been widely used for commercial and industrial purposes.

Additionally, a July 2020 Scientific Opinion from the European Food Safety Authority (EFSA) concluded that PFOS, PFOA, PFNA, and PFHxS can cause developmental effects and may have adverse effects on serum cholesterol, the liver, the immune system, and birth weight. EFSA considered the effects of PFAS on the immune system as the most critical, and established a group tolerable weekly intake (TWI) of 4.4 nanograms per kilogram of body weight (ng/kg) per week for the sum of PFOS, PFOA, PFNA, and PFHxS.

EFSA also concluded that the EU population's exposure to PFOS, PFOA, PFNA, and PFHxS exceeds the determined TWI. The bioaccumulation of PFAS in the environment, as well as the use of PFAS in food contact materials, have led to increasing human exposure to the chemicals.

U.S. FOOD & DRUG ADMINISTRATION

FDA Updates Manufactured Food Regulatory Program Standards

FDA has issued revised food safety standards for state regulatory programs that oversee food facilities that manufacture, process, pack, or hold foods. The regulatory program standards, known as the Manufactured Food Regulatory Program Standards (MFRPS), were first issued by the agency in May 2007. The 2022 changes include updates to defined terms and new job aides, as well as updates to the current standards.

MFRPS are intended to achieve basic equivalency in food safety standards and laws, and in inspection programs and practices among state and federal regulators. The standards are a critical component in establishing the national Integrated Food Safety System. The goal of MFRPS is to implement a nationally integrated, risk-based food safety system focused on protecting public health. MFRPS establishes a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of manufactured food regulatory programs in the U.S.

MFRPS comprise ten standards designed to protect the public from foodborne illness and injury. The standards include the program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment.

Food Allergy Canada

Food Allergy Canada Releases Allergen Management Guidelines, Focus on Labeling

Food Allergy Canada has released its Allergen Management Guidelines for Food Manufacturers, which includes online training and a user guide. The guidelines aim to support Canadian food and beverage manufacturers in managing allergens in their facility, enhancing food safety for consumers with allergies. Considered a chemical hazard, allergens must be effectively managed throughout the food and beverage manufacturing process with preventive control measures, in accordance with the Safe Food for Canadians Act.

Food Allergy Canada, in collaboration with Université Laval's Food Risk Analysis and Regulatory Excellence Platform, Maple Leaf Foods, and leading food manufacturers, developed the guidelines to help Canadian food and beverage manufacturers manage allergens in their facilities and guide their decisions on the appropriate use of precautionary allergen labeling. The Allergen Management Guidelines provide a framework for Canadian food and beverage manufacturers on how to develop an allergen control plan or assess their current plan within their facilities. The guidelines also include recommendations on the use of precautionary allergen labeling to ensure it can be used as an effective risk communication tool.

The guidelines offer Canadian manufacturers a risk-based approach to manage food allergens, with the aim to meet Canadian food regulatory requirements while aligning with the most recent international advice from the World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) Expert

Consultation on food allergen risk assessment methodologies and allergen thresholds.

People & Places

Felicia Wu, Ph.D., a John A. Hannah Distinguished Professor and an international expert on food safety at Michigan State University, has been appointed president-elect of the international organization Society for Risk Analysis.

In late December, the U.S. Senate confirmed **Douglas J. McKalip** as Chief Agricultural Negotiator for the Office of the U.S. Trade Representative.

NSF has promoted **Samuel Cole** to Director of Product Certification—Equipment and Chemical Evaluation, Global Food Division and **Sonia Acuña-Rubio**to Director of Food Product Certification, Global Food Division.

Key Technology has appointed **Jack Lee** as President, Key Technology—Americas.

Jesse Lyon, partner at Davis Wright Tremaine LLP, and **David Lusk**, retired Principal (non-audit Partner) with Deloitte, have joined the Advisory Board of CuliNEX in January 2023 for a two-year term.

Paul Slupecki has been appointed as Head of TOMRA Fresh Food, following the reorganization of TOMRA Food into two business areas, TOMRA Fresh Food and TOMRA Processed Food. He was previously TOMRA Fresh Food's Vice President, Head of Global Sales.

Kemin has appointed **Zheng Yang, Ph.D.** as Director of Research and Development for its food technologies business unit in North America.

BizTracks

3M Will Stop PFAS Manufacturing by End-2025

3M intends to exit per- and polyfluoroalkyl substance (PFAS) manufacturing and work to discontinue the use of PFAS across its product portfolio by the end of 2025. PFAS have come under scrutiny for their associated human health risks, as well as their indefinite persistence in the environment. PFAS are often used in food contact materials and food packaging; however, some companies have begun to phase out the use of PFAS in such applications, and governments are beginning to regulate the substances in foods and food contact materials more strictly.

3M will discontinue manufacturing all fluoropolymers, fluorinated fluids, and PFAS-based additive products. The company intends to help facilitate an orderly transition for customers, as well to fulfill current contractual obligations during the transition period. 3M has also begun reducing its use of PFAS over the past three years through ongoing research and development, and will continue to innovate new solutions for customers.

Gluten Intolerance Group Sponsors Gluten-free B2B Directory

The Gluten Intolerance Group (GIG) has announced its sponsorship of the Nourished Group's Gluten-Free Business-to-Business (B2B) Directory. Launched in January 2023, the Gluten-Free B2B Directory is the first comprehensive supply chain database for the gluten-free industry. Nourished Group launched the directory to connect manufacturers of gluten-free products to ingredient suppliers and services across the supply chain. The directory is free to use for manufacturers seeking contacts with ingredient suppliers, manufacturing services such as copackers and commercial kitchens, packaging and labeling sources, and business services that include everything from testing suppliers to Amazon specialists.

USDA Harmonized GAP+ Receives GFSI Technical Equivalence

The Global Food Safety Initiative (GFSI) and the U.S. Department of Agriculture have announced that the USDA Harmonized Good Agricultural Practices (GAP) Plus+, Version 3.0 audit standard has achieved Technical Equivalence acknowledgement against GFSI Benchmarking Requirements, Version 2020. The acknowledgement encompasses GFSI scopes "Farming of Plants" (other than grains and pulses) and "Pre-Process Handling of Plant Products."

Technical Equivalence is a category of the GFSI benchmarking process dedicated to government standards. The process recognizes the equivalence of a standard's content to the relevant scope(s) of Part III of the GFSI Benchmarking Requirements. The acknowledgement by GFSI confirms that USDA's Harmonized GAP Plus+ audit program for specialty crops is ensuring that the U.S. specialty crop sector is delivering safe products to global consumers.

Tilia Sells HPP Provider Universal Pure

Tilia Holdings LLC has sold its portfolio company, Universal Pure Holdings LLC, to Aurora Capital Partners. Universal Pure is a provider of food safety solutions for cold chain human and pet food. As an independent provider of high-pressure processing services (HPP) in North America, the company's suite of supply chain services help to ensure the safety and quality of food and beverage products.

ONLINE & OF NOTE

New Online Courses on *Codex Alimentarius*

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have produced a new series of eLearning courses on *Codex Alimentarius*. The courses are available to anyone who wishes to gain a better understanding of the *Codex* collection of food standards. The courses are suited for *Codex* Contact Points, government officials, food producers, consumer representatives, *Codex* observer organizations, and members of the scientific community. The courses are open access, available in several languages, and can also be downloaded.

The new series of eLearning serves as an interactive tool to improve stakeholders' knowledge on a range of topics to more effectively participate in the *Codex Alimentarius* Commission standard-setting process. The modular nature of each course allows learners to develop their knowledge according to their specific needs, interests, and time availability. Upon successful completion, a digital badge is issued to certify the competencies acquired in each course.

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Food Safety Objectives: The Nexus among Preventive Controls, Validation, and Food Safety Assurance

The Food Safety Objective concept is compatible with the foundational precepts of process validation

Proving food safety is a monumental challenge, if not an impossibility. However, with the appropriate tools and techniques one can confirm, with a high degree of statistical confidence, the effectiveness of a preventive control for reducing a specified hazard to an acceptable level or concentration that is consistent with achieving public health objectives.

The idea of the food safety objective (FSO) is relatively new. It was first introduced by the International Commission on Microbiological Specifications for Foods (ICMFS) in 2002 and then by the *Codex Alimentarius* Commission in 2004.[1] The concept has not been in existence as long as HACCP or the principles of process validation. Fundamentally, the FSO concept "...translates public health risk into a definable goal: A specified maximum frequency and/or concentration of a hazard in a food at the time of consumption, which is deemed to provide an appropriate level of health protection (ALOP)."[1] This approach enables food safety scientists to both define and meet a specific FSO by the application of the principles of HACCP and process validation procedures. The FSOs, then, are the pre-determined specifications or acceptance criteria by which the success of the validation procedure is objectively measured. The FSOs also provide a scientific basis that allows industry to select and implement measures that control the hazards (Critical Control Points) of concern in a specific food or food processing operation.

Likewise, this concept enables regulators to better develop and implement inspection procedures to assess the adequacy of control measures implemented by industry, and to quantify the equivalence of inspection procedures in different countries.[1,2] Thus, the practical value of using the FSO concept is that it offers flexibility of operation. It does not prescribe the preventive control measures or how an operation achieves compliance; rather, it defines the goal.[1,2] The U.S. Food and Drug Administration's (FDA's) Juice HACCP Regulations are a perfect example of the flexibility offered by the FSO. The agency established an accepted level of health protection (ALOP) (5 $\log_{10}$ reduction of *E. coli*), but it did not mandate the method for its attainment.[3] Remember, however, that the method of attainment (the preventive control) must be validated. In this case, the FSO can serve as the predetermined specification (or the objective measure) for confirming food safety assurance.

According to the 2011 Food Safety Modernization Act (FSMA), "Preventive controls are reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would reasonably employ to significantly reduce or minimize the hazard identified in the hazard analysis, and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis."[4] In the years since the passage of FSMA, there has been an ongoing and often robust discussion about the concept of a preventive control. The truth is that preventive control is not a novel concept in the context of food safety. On the contrary, the idea for preventive control has long been recognized as a fundamental tenet and an underpinning principle of modern food safety science.

For more than 60 years, the Hazard Analysis and Critical Control Point (HACCP) system for process control and food safety assurance, for example, was predicated on the ideas of risk assessment and preventive control.[5] Likewise, the former GMP regulations [(21 CFR 110.80(b)(2)(3)], since 1986, have enshrined in FDA law the notion that provided preventive measures will preclude the outgrowth of undesirable microorganisms in the production and processing of foods intended for human consumption. Those regulations list measures like thermal processing, acidification, water activity control, pasteurization, and irradiation as examples of preventive control measures.

The low-acid canned food regulation, since 1973, has codified the many requirements necessary for the effective use of thermal processing as an aegis against the formation of deadly botulinum neurotoxin in this potentially hazardous class of products. As a direct result or outcome of the low-acid canned foods regulations, the incidence of death, worldwide, attributed to botulism in commercially processed canned food is nearly nonexistent. Between 1990 and 2000, 160 foodborne botulism events affected 263 people in the U.S., representing an annual incidence rate of 0.1 per million. The vast majority of these incidents involved noncommercial (home-prepared) food products.[6] Yet, with a long history of use, the defining principle undergirding the idea of preventive control seems to not have been fully appreciated and embraced by the industry. This is one reason for the renewed emphasis on preventive controls by FDA as codified in FSMA regulations.

What is new about preventive controls in FSMA is the requirement for validation. When a preventive control measure for an identified food safety hazard is defined in the context of a food safety plan, that control measure must be validated. This aspect of the FSMA presents a more difficult and challenging subject for both FDA and the food processing industry. Until the passage of FSMA, FDA did not have a standardized, codified definition for validation. It is interesting to note that in FDA's original writing of part 110 (title 21) of the Code of Federal Regulations—Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food—the word 'validate' or 'validation' is never used. This concept was not codified in any of the food safety regulations under the Center for Food Safety and Applied Nutrition's (CFSAN's) purview. By contrast, FDA's medical devices division has published an official definition for validation since the 1980s. Many food safety practitioners, prior to 2011, have relied on this definition for guidance in the design and execution of validation protocols and related procedures.

Validation

The definition for validation from FDA's medical devices division reads, "Validation is the process of establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications for quality and food safety."[7] The new FSMA definition for validation reads somewhat differently: "Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards."[8] The bedrock principle supporting validation is the requirement for proving a process or procedure capable of delivering against a pre-determined, specified outcome with a high degree of statistical certainty and reproducibility. Interestingly, FDA's current definition appears to be missing these fundamental prerequisites of validation.

Much like FDA, the *Codex Alimentarius* of the World Health Organization (WHO) also did not have a codified definition for validation until 2013. The *Codex* definition closely resembles the earlier (1980s) version from FDA's medical devices division. The *Codex* definition speaks to both capability and controlling the hazard to a specified outcome.[9]

The purpose of validation, in the final analysis, is confirmation of food safety assurance corresponding with an established and accepted level of risk. "Judging food safety is judging acceptability of risk."[10] It can be logically concluded that the aim of validation is to demonstrate that a preventive control measure will reduce the identified food safety threat to an acceptable level or concentration, thereby allowing the food's consumption without incurring an excessive risk of injury, morbidity, or mortality.[10] The concept of a predetermined specification (output) is an essential, fundamental element of validation. Validation is also the link that connects the FSO concept with preventive control schemes, such as HACCP or HARPC. The following diagram, while not mathematical in the literal sense, proposes a relationship between the elements of process validation (IQ + PQ + OQ), critical control points (CCP), performance objectives (PO), the FSO concept, and ALOP. A more detailed discussion of these relationships is presented in subsequent paragraphs.

$$\sum (IQ + PQ + OQ) = \sum CCP \to PO \le FSO = ALOP$$

Public Health Protections and the FSO

Establishing an FSO for a specific hazard requires risk evaluation of the public health threat associated with the specific hazard in a food. The risk assessment may be derived by advice from a few specialists, by larger expert panels, or by conducting a quantitative risk assessment.[11] For example, an expert panel might conclude that an exposure rate of one case in 1 million people, for substance *X*, at a concentration of 1 ppb per 50-gram serving, is the threshold for its safety in a particular food. This threshold is frequently referred to as the ALOP. The ALOP is an excellent means of communicating the relative risk, but it is a difficult measure by which to judge the efficacy of food manufacturing and control processes. Consequently, at the process and control level, the ALOP has little real value.[11] By contrast, the FSO concept translates the ALOP to a definable goal, such as performance objectives (PO) and performance criteria (PC). The PO describes and delimits how a process is to work,[11] whereas performance criteria are the objective measures used for confirming that the process is actually working.[11] For example, the PO might describe the functioning of a CCP, and the PC would correspond to the critical limits assigned to that particular CCP.

The term FSO is applicable to situations where either a concentration of a hazard is set (e.g., less than 100 cfu of *L. monocytogenes* per gram of ready-to-eat food) or where a frequency is expressed (e.g., less than one per hundred (100 ml) servings of fresh apple cider contains *Salmonella*).[2] In a 2005 paper,[2] Marcel Zwietering provides a compelling example on converting an established ALOP for *L. monocytogenes* in raw milk cheese (one death per 1 million per year) to an FSO ≤ 2 $\log_{10}$ cfu/gram of the viable organism in the cheese at the point of consumption.[2] Therefore, hypothetically, assuming an $[H_0]$ = 6 $\log_{10}$/cfu/gram, then a thermal process of 71.5 °C for 30 seconds might be used as an effective preventive control. In another paper, the authors provide an insightful discussion on the application of the FSO concept to thermally processed canned foods.[12]

The FSO concept can be described by the following equation:[1,2,11]

$$[H_0] - \sum R + \sum I \le FSO$$

Where:

$[H_0]$ = Initial concentration of the identified hazard

$\sum R$ = Effect of the specified process in reducing the concentration of the hazard

$\sum I$ = Denotes any incipient increase in the hazard during processing and handling

Note that each factor of the equation is expressed in $\log_{10}$ units.

Definitions and the correct representation of units is of considerable importance when communicating an FSO. Zwietering has offered the following significant observations in this regard:[2]

- To avoid misunderstanding, one should always clearly distinguish between concentration and dose, and it is important to report units in the correct way: concentration (organisms per gram) or dose (organisms per serving; for example, 100 g, which differs by a factor of 100).
- One should clearly define the endpoint and the corresponding or appropriate units of risk: whether it is infection, illness, or death (endpoint), and the population that is considered. Whether risk is measured as health outcome per consuming occasion, year, or lifetime exposure is of large importance. This seems obvious, but in many publications the unit is not given; therefore, much more emphasis on the correct reporting is necessary. Reporting of a number without defining the "case," the population on which it is based, and the time frame is of no use.

> "The Food Safety Objective concept supports the longstanding rudimentary tenet of food safety assurance—that food safety is a product- and process-specific activity."

The FSO concept is also compatible with the foundational precepts of process validation. Moreover, the concept supports the longstanding rudimentary tenet of food safety assurance—that food safety is a product- and process-specific activity.

HACCP, the much-heralded food safety and process control strategy, first codified by FDA regulations in 1986, is predicated on the idea of identifying and validating a CCP in a food manufacturing process. The CCP is also the preventive control measure. To be effective, the CCP must have a quantifiable level of effectiveness relative to the specific hazard. This level of effectiveness is referred to as the CCP's critical limit. In other words, the preventive control associated with the CCP must be capable of reducing the identified hazard to a level that is consistent with public health protection (ALOP). For example, FDA's juice HACCP regulations have identified as the critical limit a 5 $\log_{10}$ reduction of *E. coli* in juice products.[3] Thus, the CCP and its attendant preventive control measure must operate at a minimum level of efficacy that will ensure attainment of this specified performance outcome.

HACCP is based on the principle of risk reduction and confirmation (with a high degree of confidence) that the CCP is capable of mitigating the identified threat to food safety. The effectiveness of the CCP is determined by the efficacy of the device, procedure, or process to which the critical limit is assigned. A sieve, for example, will preclude only dangerous extraneous materials when the size and geometry of that hazardous material is greater than the diameter of the individual holes in the body of the sieve. Why, then, given the potential effectiveness of HACCP as a process control strategy for assuring safe food, has FDA moved away from this system in favor of what the agency is now calling Hazard Analysis Risk Assessment and Preventive Controls (HARPC)?

This is an intriguing question. There does not appear to be, in a material sense, any substantive difference between the two food safety strategies. After all, risk assessment (hazard analysis) and prevention are the hallmarks of the HACCP system. It has been suggested that FDA may have sought to "rebrand" HACCP in order to promote other aspects of FSMA. Important among these distinctions between HACCP and HARPC is mandatory validation of preventive control measures. Since 1986, with the update of the current GMP regulations, many companies embraced HACCP on a voluntary basis. Due to the voluntary adoption of HACCP, however, the systems were developed in isolation and absent a compulsory regulatory review. The plans were developed subject to each company's interpretation of the HACCP process and often guided by the arbitrary standards of myriad HACCP certification schemes. Experience further suggests that many companies developed food safety plans, but only a few of these companies actually implemented the HACCP system. Hence, HACCP was reduced to several pages of paper, held in so many binders, and found only in the quality control manager's office. There was little to no evidence for the existence of HACCP on the production floor. Rebranding of HACCP as HARPC appears to have been viewed, by FDA, as a strategy to standardize and further regulate HACCP across the food industry. Meanwhile, *Codex* and other regulatory agencies external to the U.S. have maintained their commitment to the development and implementation of HACCP.

Process Validation

Validation of preventive control measure(s) is the preeminent and distinguishing feature of FSMA legislation. Validation can also be a major challenge and a source of great confusion for both industry and the regulatory agency. Certainly, it is the most demanding in terms of both scientific rigor and resources. When properly executed, validation considers the impact of an entire process in achieving the specified food safety outcome. The Kellogg's logic model[13] is a simple but eloquent way of dissecting the rudimentary elements of a food process. The basic components of that model include input, activity, and output. Most, if not all, processes have these elements or sequential steps in common (Figure 1).

Input is the place in the process where the risks are concentrated. Involved here, for example, are sensitive raw materials, additives, ingredients, and packaging. The risks associated with the input are normally transferred, unabated, to the next step in the process. The *activity* step is intended, by design, to reduce the risk to an acceptable level that is consistent with public health expectations. Thus, the *output* of that process, when the activity step is properly applied and controlled, should be food that is safe for human consumption.

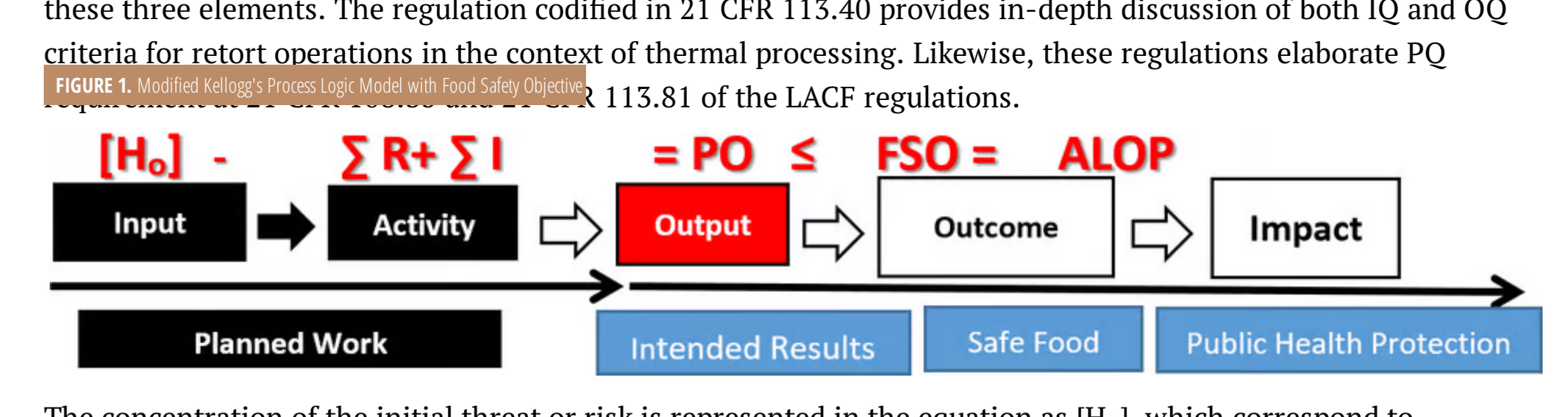
This entire paradigm is valid only when the activity phase of the process is capable of attenuating the original concentration of the inbound hazards to safe and acceptable levels. In other words, the activity phase would have been the subject of a deliberate, science-based study that has confirmed (again, with a high degree of confidence) that it is effective in controlling the identified food safety hazard. The science-based study would have considered both the inbound risk (input) and any residual risk remaining in the output of the process. Conducting and assessing the capability of the activity phase (preventive control) requires that three separate assessments or qualifications are initiated: installation qualification (IQ), operational qualification (OQ), and process qualification (PQ). For example, when a new high-pressure processing (HPP) machine that is intended for use as a post-process decontamination step in deli meat is installed, the IQ, OQ, and PQ assessments would be performed prior to using the HPP device in production. These qualification processes are the fundamental phases of process validation:

- IQ: Establishing confidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances
- OQ: Establishing confidence that the process is effective and reproducible
- PQ: Establishing confidence, through appropriate testing, that the finished product produced by a specified process meets all predetermined release requirements for functionality and safety.

It might also be inferred, then, that **∑ (IQ + OQ + PQ) = − ∑ R + ∑ I = PO ≤ FSO**. This relationship represents the endpoint in quantifying the preventive capacity of the process and the attainment of the predetermined specification for food safety, which is the ultimate aim of the validation process. To be effective, the preventive control capacity of a CCP must yield a residual level of risk in the output of the process that is less than or equal to the threat level specified by the FSO.

FDA's Low Acid Canned Foods Regulations, for example, include specifications and other requirements for each of these three elements. The regulation codified in 21 CFR 113.40 provides in-depth discussion of both IQ and OQ criteria for retort operations in the context of thermal processing. Likewise, these regulations elaborate PQ [illegible] 113.81 of the LACF regulations.

FIGURE 1. Modified Kellogg's Process Logic Model with Food Safety Objective



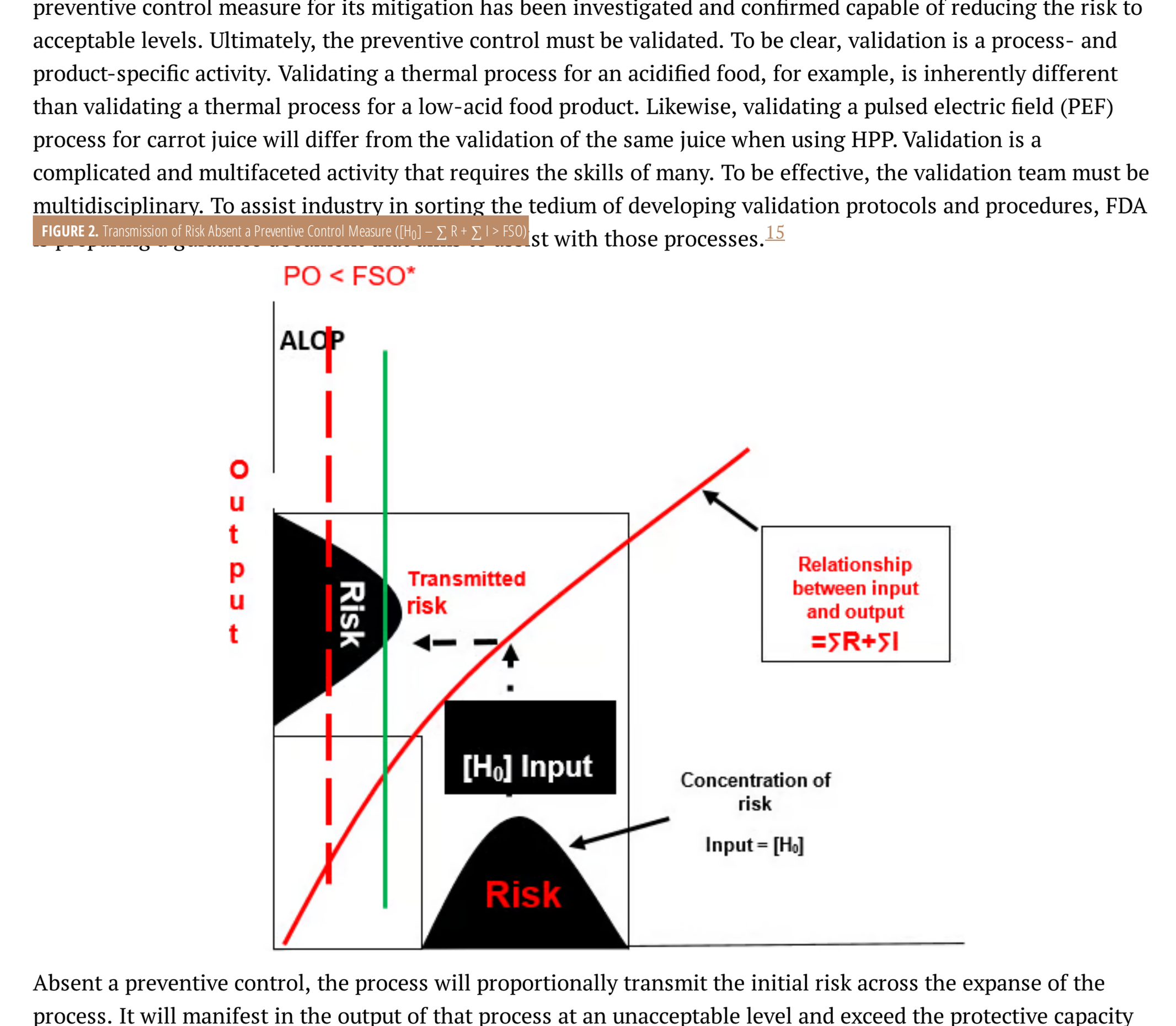
The concentration of the initial threat or risk is represented in the equation as $[H_0]$, which correspond to accumulated risk associated with the input to the process. The activity phase of the process represents the CCP and its associated preventive control measure(s). These are represented by $- \sum R + \sum I$ in the equation, where *R* equals the reduction capacity of the control measure and *I* allows for the possibility of an incipient increase in the threat, occurring during the interval required for the application of the control measure(s). The output of the process represents food that is fit for human consumption and corresponds with a PO or FSO that is less than the ALOP for food safety.

FDA has understood and long advocated process control as the means for achieving food safety assurance. The three points below eloquently state the agency's position. Point 3 is especially compelling in this regard. Dr. Deming noted the same truth when he said, "Test and inspect your processes, not your finished products."[14]

1. Safety, quality, and effectiveness must be designed and built into the product
2. Safety cannot be inspected or tested into the finished product
3. Each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all safety, quality, and design specifications.

Food safety assurance derives in great measure from the systematic use of highly controlled manufacturing processes, where the nature of the food safety risk is identified and characterized and, furthermore, that the preventive control measure for its mitigation has been investigated and confirmed capable of reducing the risk to acceptable levels. Ultimately, the preventive control must be validated. To be clear, validation is a process- and product-specific activity. Validating a thermal process for an acidified food, for example, is inherently different than validating a thermal process for a low-acid food product. Likewise, validating a pulsed electric field (PEF) process for carrot juice will differ from the validation of the same juice when using HPP. Validation is a complicated and multifaceted activity that requires the skills of many. To be effective, the validation team must be multidisciplinary. To assist industry in sorting the tedium of developing validation protocols and procedures, FDA [illegible] with those processes.[15]

FIGURE 2. Transmission of Risk Absent a Preventive Control Measure ($[H_0] - \sum R + \sum I > FSO$)



Absent a preventive control, the process will proportionally transmit the initial risk across the expanse of the process. It will manifest in the output of that process at an unacceptable level and exceed the protective capacity specified by the FSO (Figure 2). In this type of process, there is no palladium (UCL) to prevent the manifestation of the harmful effects in the finished product. This is an example of a process that is incompatible with achieving food safety. Said in more simplistic terms, "bad stuff in equals bad stuff out."

FIGURE 3. Transmission of Risk with a Validated Preventive Control Measure ($[H_0] - \sum R + \sum I < FSO$)

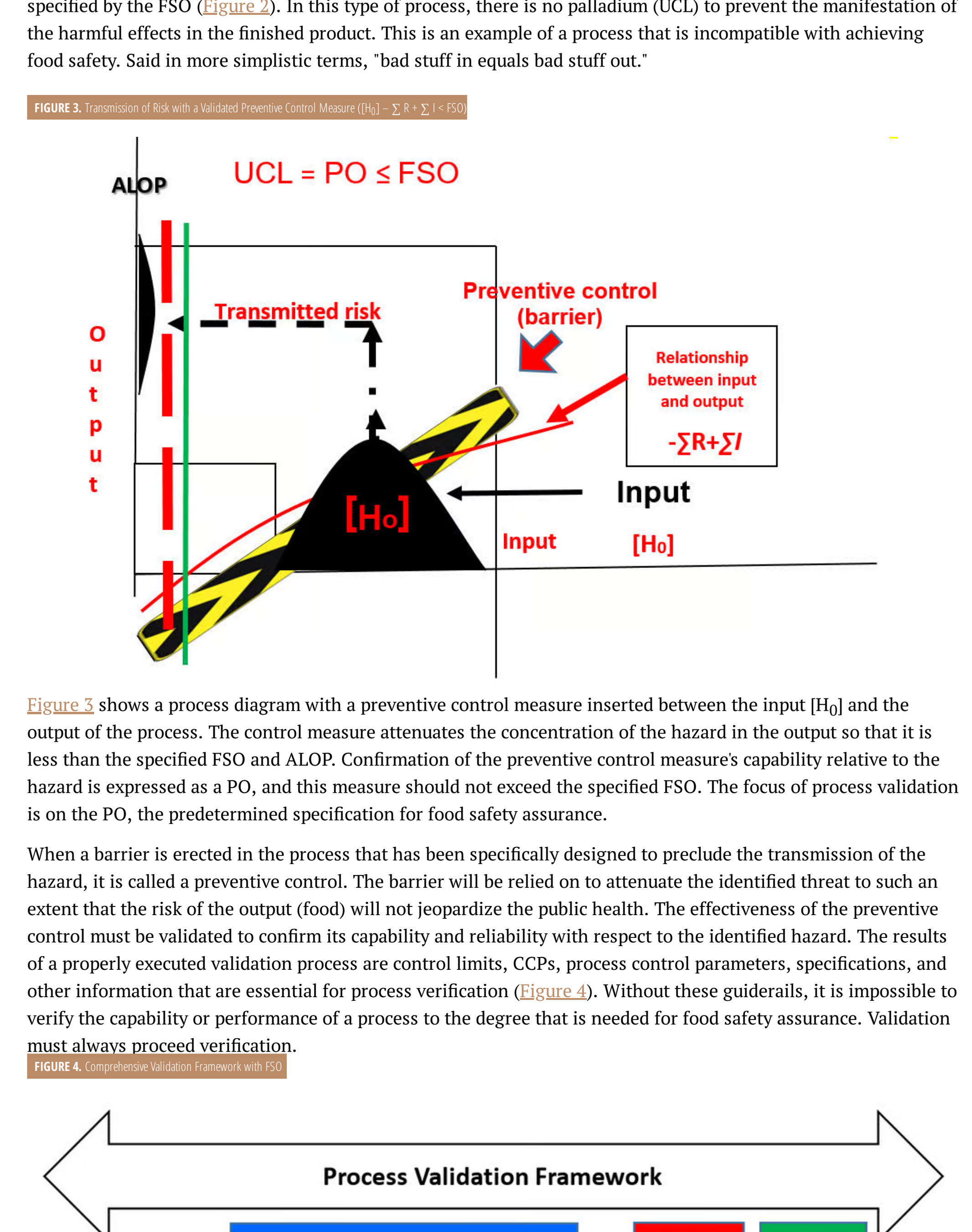
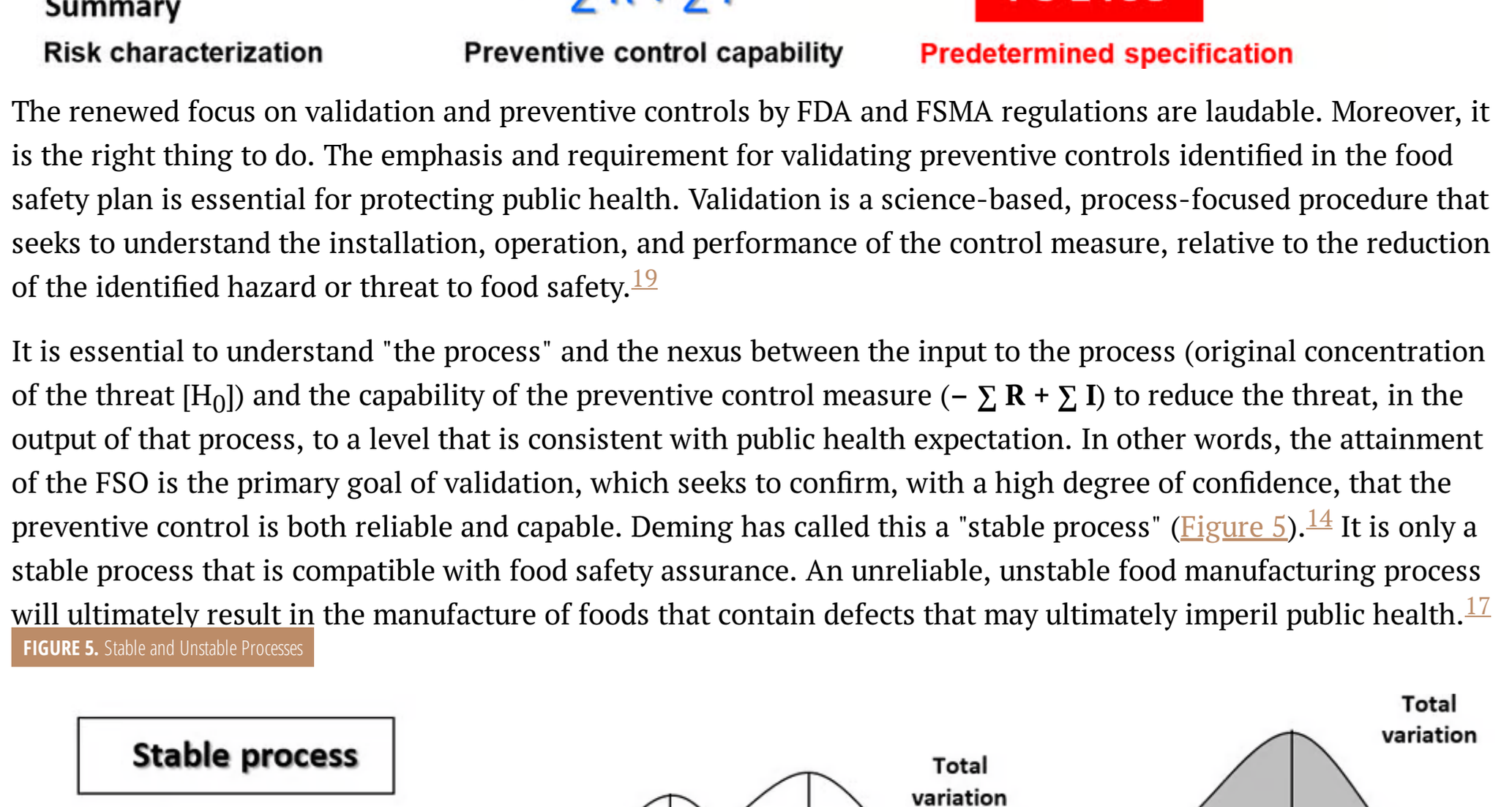


Figure 3 shows a process diagram with a preventive control measure inserted between the input $[H_0]$ and the output of the process. The control measure attenuates the concentration of the hazard in the output so that it is less than the specified FSO and ALOP. Confirmation of the preventive control measure's capability relative to the hazard is expressed as a PO, and this measure should not exceed the specified FSO. The focus of process validation is on the PO, the predetermined specification for food safety assurance.

When a barrier is erected in the process that has been specifically designed to preclude the transmission of the hazard, it is called a preventive control. The barrier will be relied on to attenuate the identified threat to such an extent that the risk of the output (food) will not jeopardize the public health. The effectiveness of the preventive control must be validated to confirm its capability and reliability with respect to the identified hazard. The results of a properly executed validation process are control limits, CCPs, process control parameters, specifications, and other information that are essential for process verification (Figure 4). Without these guiderails, it is impossible to verify the capability or performance of a process to the degree that is needed for food safety assurance. Validation must always proceed verification.

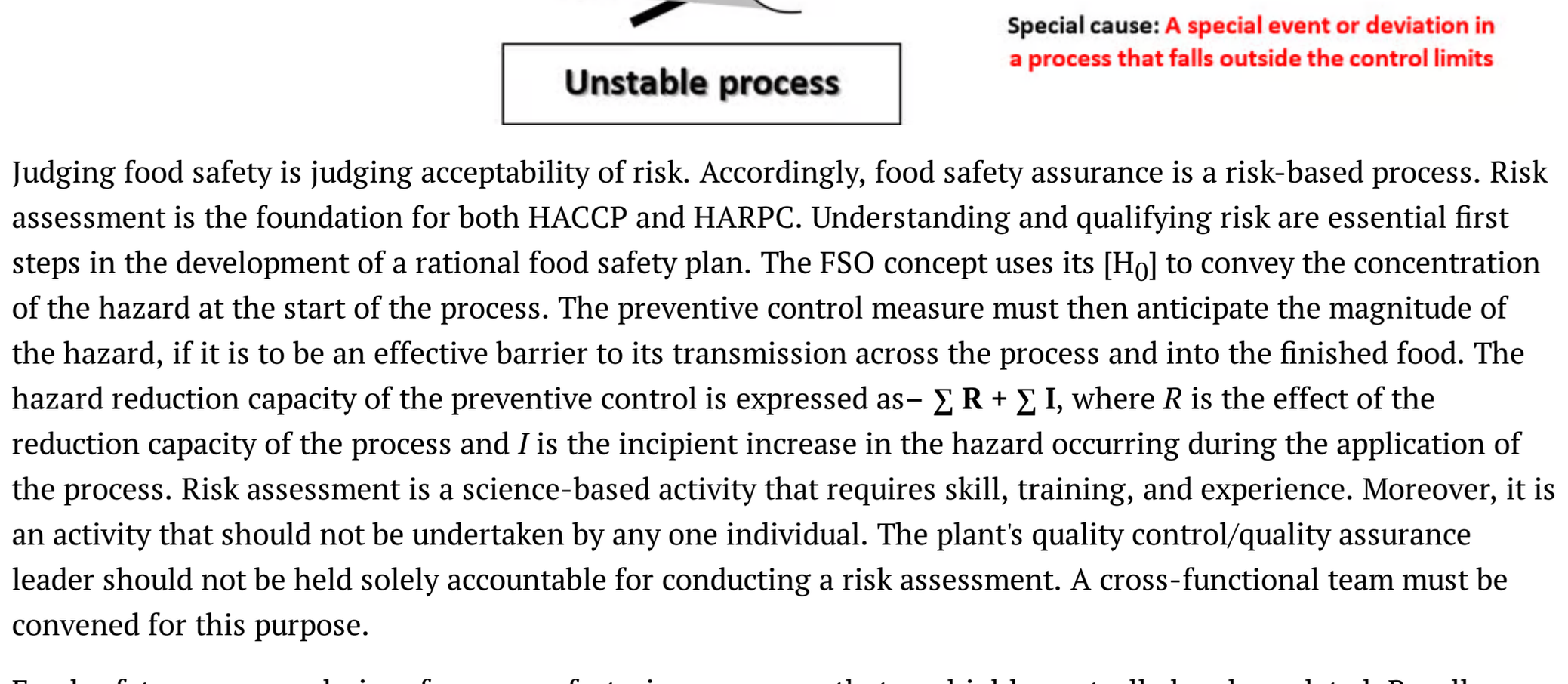
FIGURE 4. Comprehensive Validation Framework with FSO



The renewed focus on validation and preventive controls by FDA and FSMA regulations are laudable. Moreover, it is the right thing to do. The emphasis and requirement for validating preventive controls identified in the food safety plan is essential for protecting public health. Validation is a science-based, process-focused procedure that seeks to understand the installation, operation, and performance of the control measure, relative to the reduction of the identified hazard or threat to food safety.[19]

It is essential to understand "the process" and the nexus between the input to the process (original concentration of the threat $[H_0]$) and the capability of the preventive control measure (**− ∑ R + ∑ I**) to reduce the threat, in the output of that process, to a level that is consistent with public health expectation. In other words, the attainment of the FSO is the primary goal of validation, which seeks to confirm, with a high degree of confidence, that the preventive control is both reliable and capable. Deming has called this a "stable process" (Figure 5).[14] It is only a stable process that is compatible with food safety assurance. An unreliable, unstable food manufacturing process will ultimately result in the manufacture of foods that contain defects that may ultimately imperil public health.[17]

FIGURE 5. Stable and Unstable Processes



Judging food safety is judging acceptability of risk. Accordingly, food safety assurance is a risk-based process. Risk assessment is the foundation for both HACCP and HARPC. Understanding and qualifying risk are essential first steps in the development of a rational food safety plan. The FSO concept uses its $[H_0]$ to convey the concentration of the hazard at the start of the process. The preventive control measure must then anticipate the magnitude of the hazard, if it is to be an effective barrier to its transmission across the process and into the finished food. The hazard reduction capacity of the preventive control is expressed as **− ∑ R + ∑ I**, where *R* is the effect of the reduction capacity of the process and *I* is the incipient increase in the hazard occurring during the application of the process. Risk assessment is a science-based activity that requires skill, training, and experience. Moreover, it is an activity that should not be undertaken by any one individual. The plant's quality control/quality assurance leader should not be held solely accountable for conducting a risk assessment. A cross-functional team must be convened for this purpose.

Food safety assurance derives from manufacturing processes that are highly controlled and regulated. Recall, then, that ALOP is of little value at the point of process control. The FSO or PO are better measures, in terms of food safety assurance, for assessing process control capability. These measures can also be validated. Achieving food safety demands superb and complete understanding of manufacturing processes, particularly their IQ, OQ, and PQ performance against predetermined specifications for food safety. Testing the finished product for food safety adds no value; at that point it is too late—the food is either good or bad,[14,17,18] safe or unsafe, and no amount of product testing will alter the truth of this sapient observation.

Judging food safety demands an objective arbiter. The measures by which those judgements are made must be based on sound science and properly validated.[20] Otherwise, catastrophic process failures may occur, posing a very real potential for harm to public health. Information is never a substitute for illumination. An ALOP is information. Validation is the illumination of process capability, and POs, CCPs and FSOs are its signposts of success.

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DIGITAL VISION

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A New Era for Food Allergen Analysis? Shifting Focus from Detection to Accurate and Precise Quantification

Method considerations and data gaps must be addressed in the shift toward quantitative, risk-based allergen management strategies

Food allergens are critical food safety hazards for manufacturers, regulators, and allergic consumers. Despite many improvements in recognition of the importance of food allergen management, undeclared food allergens remain the most frequent cause of recalls in the U.S. At the same time, there has been no apparent slowdown in the use of precautionary allergen labeling (PAL), also commonly known as 'may contain' labeling. To some extent, both outcomes result from the absence of regulatory thresholds for food allergens, which leads to zero-tolerance approaches to allergen management decisions.

Risk-based approaches for food allergens offer a path forward for both allergen management and PAL decision-making. After many years of research, a clearer picture has emerged of the population-level, threshold-dose distributions for major food allergens using data generated in double-blind, placebo-controlled food challenge studies. In other words, the risk assessment community has a better understanding of the amounts of food allergens that are likely to cause reactions in allergic individuals. Notable initiatives to ensure the implementation of risk-based approaches for food allergens include the Voluntary Incidental Trace Allergen Labelling (VITAL) Program from the Allergen Bureau, and ongoing meetings of the ad hoc Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Consultation on Risk Assessment of Food Allergens. These efforts have provided clarity on the application of scientific evidence for food allergen risk assessment, which may ultimately lead risk managers and regulatory authorities to develop quantitative action levels for food allergens. If action levels are established, a critical question will be: Can we reliably and accurately quantify food allergens at those action levels?

The current zero-tolerance framework provides minimal impetus for end users to focus on the precision and accuracy of quantitative results. If any detection of undeclared allergen in finished product is considered unacceptable, does it really matter if the relative standard deviation (RSD) of the method is 20 percent, 50 percent, or 100 percent? On the other hand, if action levels are established for food allergens, then both the accuracy and precision of methods become critical performance parameters. The decisions that can be made with a method that demonstrates 10 percent recovery and 50 percent RSD are quite different from decisions based on a method with 80 percent recovery and 15 percent RSD. If the food allergen management field is headed for a shift toward quantitative, risk-based management strategies, then several method considerations and important data gaps must be addressed.

Food Allergen Methods

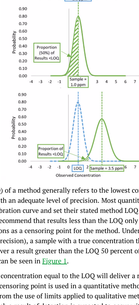
The most common methods for food allergen analysis are immunoassays, including both quantitative ELISA methods and qualitative lateral flow devices. Immunoassays utilize antibodies that specifically recognize proteins from the food allergen material of interest. In general, immunoassays can have high degrees of both specificity and sensitivity—important characteristics for food allergen methods, which need to be able to detect low concentrations of proteins from one allergenic food in matrices containing a diverse variety of other food components. With respect to quantitative food allergen methods, sandwich ELISA methods are generally the most popular format. Commercial kits for food allergen detection or quantification are manufactured by several companies, and these commercial methods are widely used by food manufacturers and third-party laboratories. However, there are no official or reference methods for food allergens (other than gluten) against which the performance of these many different commercial kits can be compared.

Mass spectrometry (MS) is an emerging methodology for the detection and quantification of food allergens. MS methods for food allergens published to date are bottom-up proteomics methods, meaning that sample proteins are digested into peptides by specific enzymes to enable analysis in the MS instrument. The peptides serve as surrogates for the detection and quantification of proteins from the allergenic food of interest. MS methods can demonstrate similar, or better, specificity and sensitivity performance compared to ELISA methods. In many situations, the fact that MS methods detect specific peptides, rather than relying on antibody binding, is the source of advantages over immunoassays. Specifically, MS methods are not affected by changes to protein conformation that may occur during processing, and rigorous extraction conditions can be used to solubilize protein aggregates inherently present in food matrices or generated during processing. Currently, however, MS methods are not used widely or routinely in food allergen analysis laboratories.

Method Performance Parameters and Limits

Despite the infrequent use of quantitative values, much of the food allergen analysis conducted on ingredients and finished food products has utilized quantitative ELISA methods, as they often have better performance with respect to recovery and specificity in complex matrices than some of their qualitative immunoassay counterparts. As more attention is placed on quantitative information for food allergens, it will be important for method and data users to understand the expected quantitative method performance criteria for these methods, including limit of quantification, recovery, and precision.

FIGURE 1. Limit of Quantitation (LOQ) at a Glance/Fig Data



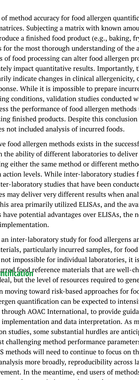
The limit of quantitation (LOQ) of a method generally refers to the lowest concentration at which the method provides a quantitative result with an adequate level of precision. Most quantitative, commercial ELISA kits, however, implement a fixed calibration curve and set their stated method LOQ as the lowest non-zero calibrant. Method instructions generally recommend that results less than the LOQ only be reported as below the LOQ. In these instances, the LOQ functions as a censoring point for the method. Under optimal method performance (e.g., 100 percent recovery, uniform precision), a sample with a true concentration that is exactly equivalent to the LOQ calibrant concentration will deliver a result greater than the LOQ 50 percent of the time and a result less than the LOQ 50 percent of the time, as can be seen in Figure 1.

In other words, a sample with a concentration equal to the LOQ will deliver a result of below the LOQ (BLQ) 50 percent of the time. Any time a censoring point is used in a quantitative method, this will be the case. This situation is distinctly different from the use of limits applied to qualitative methods, where the detection limit indicates a concentration at which a result of detection is expected to occur with a given frequency, typically 90–100 percent probability of detection. For quantitative methods, only samples containing analyte concentrations greater than the LOQ would be expected to consistently deliver results greater than the LOQ.

Another critical method performance parameter for quantitative food allergen methods is recovery. Over the past several decades, numerous studies have indicated that many different factors, including matrix composition and food processing, can impact the quantitative recovery of food allergens. For the purposes of method validation, many consider 80–120 percent recovery to be optimal, but 50–150 percent recovery is generally acceptable for food allergen methods given the many complex scenarios involved. For many matrices undergoing extensive thermal processing, however, it is not unusual to observe recovery values far less than 50 percent with current analytical methods. In the case of fermented or hydrolyzed products, very low, if any recovery is observed, particularly with sandwich ELISA methods.

When considering method validation information, it is critical to determine whether reported recovery values were determined from analysis of incurred foods or spiked samples. Incurred foods have food allergen materials incorporated into the matrix formulation prior to any relevant processing used to generate finished product test samples. Spiked samples, on the other hand, have food allergen materials incorporated into a finished food matrix that has not been subjected to any processing. If a method will be used to analyze finished products, information on the quantitative recovery from incurred foods is essential.

FIGURE 2. Sample Data Set of Incurred Food Allergen Recovery Data



Precision is another parameter essential for evaluating method performance and results. For allergen methods, relative standard deviation (RSD, also referred to as coefficient of variation, CV) is commonly used to describe method precision. RSD is calculated as the observed standard deviation divided by the observed mean. For the same percent RSD values (e.g., 20 percent) at different concentrations, the outcome is larger absolute standard deviations at higher concentrations (Figure 2). It can also be informative to remember that for normally distributed data, 68 percent of data would be expected to fall within the range of the mean ± one standard deviation, while 95 percent of data would be expected to fall within the range of the mean ± two standard deviations. Given the example in Figure 2, for a method demonstrating 20 percent RSD at 25 ppm of analyte, it would not be unexpected to observe results of 15–35 ppm.

Lastly, it is important to recognize that methods have different types of precision that are relevant to end users. Repeatability standard deviation (and corresponding relative standard deviation) should indicate the variation observed when a method is conducted in its entirety under conditions where as many experimental factors as possible are kept constant (e.g., laboratory, day, analyst, equipment, test kit lot, calibration, etc.). Reproducibility standard deviation, on the other hand, indicates the variation observed when the same samples are analyzed in different laboratories. Between reproducibility and reproducibility is intermediate precision, where the same samples are analyzed in one laboratory over an extended time period, with changes in the experimental factors mentioned above. Method users should anticipate observing different levels of precision under these different conditions.

Needs and Data Gaps for Quantitative Food Allergen Methods

Among the many needs for food allergen methods to be useful in this new quantitative era, perhaps the most straightforward to tackle is the demand for meaningful, uniform reporting units. Multiple stakeholder groups have recommended that methods report results in mg of total protein from the allergenic source per kg of sample (mg/kg, or ppm, total protein from the allergenic source). These recommendations are based largely on the fact that risk assessment data are analyzed and expressed in terms of the amount of total protein from the allergenic source. Importantly, total protein from the allergenic source is not the same as soluble protein extracted under any given conditions. Total protein from an allergenic source should be measured by a nitrogen determination method capable of analyzing both soluble and insoluble protein fractions (i.e., Kjeldahl or Dumas total protein methods).

For quantitative action levels to be enforceable, there must be methods available to regulatory agencies for accurate and precise quantification. When the action levels are applicable to finished products, the methods must also be fit for purpose for the corresponding processed matrices. A notable example of the potential consequences of a lack of validated quantitative methods is the final rule on gluten-free labeling of fermented or hydrolyzed foods issued by the U.S. Food and Drug Administration (FDA). Since 2013, FDA has implemented a definition for the use of gluten-free labeling that includes a quantitative limit of 20-ppm gluten in finished products. At the time of the rule implementation, commercial methods were available that had been validated for quantification of gluten in several processed food matrices. The validations did not, however, include matrices that had gone through fermentation or hydrolysis processing, and evidence emerged that gluten was not accurately quantified in many of these instances. The FDA subsequently concluded that since no scientifically valid methods were available for quantifying gluten in fermented and hydrolyzed foods, foods and ingredients produced through fermentation and/or hydrolysis must be shown to be gluten-free prior to fermentation/hydrolysis and protected from gluten cross-contact thereafter.

As discussed above, assessment of method accuracy for food allergen quantification in finished products is best conducted using incurred food matrices. Subjecting a matrix with known amounts of food allergen to relevant food processing operations used to produce a finished food product (e.g., baking, frying, fermentation, freezing, drying, acidification, etc.) allows for the most thorough understanding of the accuracy of methods. Many studies have indicated that various types of food processing can alter food allergen protein properties, such as solubility and conformation, which ultimately impact quantitative results. Importantly, these changes in quantitative analytical results do not necessarily indicate changes in clinical allergenicity, or the ability of the food product in question to elicit an allergic response. While it is impossible to prepare incurred foods for every variation in matrix composition and processing conditions, validation studies conducted with a selection of incurred food matrices are the best way to assess the performance of food allergen methods under conditions like those experienced by end users analyzing finished products. Despite this conclusion from prior studies, the performance evaluation of many methods does not included analysis of incurred foods.

An additional gap for quantitative food allergen methods exists in the successful completion of inter-laboratory validation studies. Confidence in the ability of different laboratories to deliver similar quantitative results when analyzing the same samples, using either the same method or different methods, will be essential for the implementation of food allergen action levels. While inter-laboratory studies for some gluten ELISAs have delivered suitable results, the inter-laboratory studies that have been conducted for food allergen methods have generally shown that laboratories may deliver very different results when analyzing the same samples. The few studies that have been done in this area primarily utilized ELISAs, and the availability of data for MS methods is even scarcer. While MS methods have potential advantages over ELISAs, the near absence of inter-laboratory data is a substantial barrier to wider implementation.

The challenges with conducting an inter-laboratory study for food allergens are heightened by another deficiency, the general lack of reference materials, particularly incurred samples, for food allergen analysis. While preparation of incurred foods is not impossible for individual laboratories, it is time-consuming and labor-intensive to the point where the general food reference materials that are well-characterized, homogeneous, value-assigned, and stable would be ideal, but the level of resources required to generate such reference materials has been a barrier to their development.

Outlook for Food Allergen Quantification

Given the shift in emphasis on moving toward risk-based approaches for food allergen management, the focus on accurate and precise food allergen quantification can be expected to intensify. Efforts are underway within the analytical community, including through AOAC International, to provide guidance on both food allergen method validation and end-user method implementation and data interpretation. As more quantitative methods attempt to undergo formal method validation studies, some substantial hurdles are anticipated. In finished food products, recovery remains one of the most challenging method performance parameters to adequately meet. Method developers of both ELISA and MS methods will need to continue to focus on this aspect to improve method performance. For food allergen analysis more broadly, reproducibility across laboratories is another issue that deserves more study and improvement. In the meantime, end users of methods and/or data should recognize and account for how method performance characteristics may impact the trueness of the measured values for food allergens. ■

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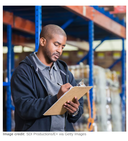
By Bob Ferguson, President, Strategic Consulting Inc.



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How the Food Traceability Rule will Impact Food Processors—Part 1

What are food processors doing to prepare for compliance with the FDA Food Traceability Rule in 2026, and how do they see it affecting their businesses?

In November 2022, the U.S. Food and Drug Administration (FDA) published its Final Food Traceability Rule, *Requirements for Additional Traceability Records for Certain Foods*,[1] as mandated by Congress under FSMA Section 204.

As stated in the rulemaking announcement released by FDA, the Traceability Rule requires companies that manufacture, process, pack, or hold foods listed on the Food Traceability List (FTL) to maintain detailed records on their supply chain and suppliers, including 'Key Data Elements' (KDEs) about how those supplies are handled and processed. The Traceability Rule regulates processors of foods on the FTL, which include fresh-cut fruits and vegetables, shell eggs, nut butters, ready-to-eat deli salads, cheeses, and seafood products. The Traceability Rule applies to foods on the FTL, but a further stated aim of the rule is to encourage the voluntary adoption of these tracing records for all food products.

It is easy to see that the Traceability Rule will have a wide-reaching impact on those food companies that produce foods listed on the FTL. However, the Rule will also have a significant impact on many other companies, regardless of whether they produce foods on the FTL, due to supply chain conformity or the imposition of commercial requirements from their customers.

For this issue's column, we wanted to find out more about food processors' thoughts on the Food Traceability Rule, the impact it will have on their businesses, and what they are doing to prepare for current expectations and for eventual full compliance with the Traceability Rule by the three-year deadline.

To find out the answers to these questions, we conducted a survey and interviews with approximately 100 companies within the U.S., Canada, and 15 other countries across eight major processing categories. Of the companies that were part of our investigation, roughly two thirds—73 percent in North America and 67 percent internationl—said that they are FDA-regulated facilities (Figure 1). Of those in North America, 88 percent said they were familiar with the regulatory changes proposed by the Rule (Figure 2). We found a lower level of awareness among

FIGURE 1. Are You an FDA-Regulated Facility?

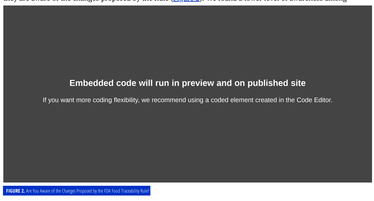
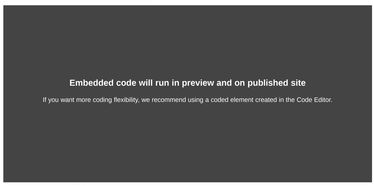
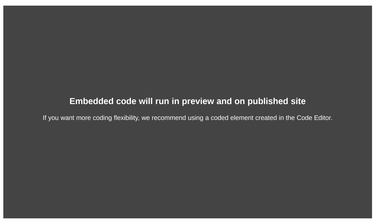


FIGURE 2. Are You Aware of the Changes Proposed by the FDA Food Traceability Rule?



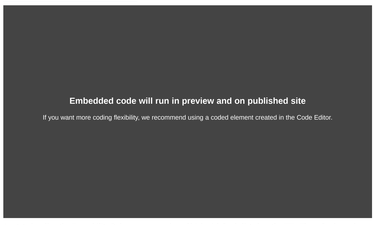
Roughly one third of all facilities (Figure 3) said they produce products on the FTL (although this may be underreported, as about the same percentage said they did not know), and 57 percent said they thought the Traceability Rule would eventually apply to other foods not listed on the FTL.

FIGURE 3. Does the Food Traceability Rule Apply to You?



We also wanted to find out processors' top concerns about the Traceability Rule and the responsibilities it will impose for compliance (Figure 4). Of those companies indicating that they are familiar with the rule, their top concerns are around application and enforcement. The comments in this category mainly concerned which foods fall under the Traceability Rule and how FDA will approach enforcement for products that appear to be covered under the FTL but are not precisely defined in the text of the Rule.

FIGURE 4. What are Your Top Concerns about the FDA Food Traceability Rule?



As stated earlier, the Traceability Rule covers a number of high-risk foods listed on the FTL. These foods can be ingredients or final products, and can exist in the supply and processing chain in a number of forms. Many survey respondents questioned which foods are specifically addressed by the Rule and what happens when a food or ingredient is potentially covered in one form but may be changed during processing to a form that is potentially not covered. Are these foods still 'high-risk,' according to the spirit of the Rule, in the way that these processors are using them? How will FDA define these products when they are used in another way, other than the exact form as described in the Rule?

One processor commented, 'We are unsure when the foods are sufficiently changed to no longer match what is described on the FTL and at what point are foods not considered 'fresh.' Another added color to the topic by mentioning, 'In our processes, we often use both whole and diced tomatoes and sometimes switch between both in a single production batch. The Rule doesn't take into account that during the manufacturing process, the whole tomatoes break down and become indistinguishable from diced tomatoes, essentially making the ingredient description irrelevant.'

Another processor questioned the applicability of the Traceability Rule to its specific operation. The Rule defines applicability to include '…companies that manufacture, process, pack, or hold foods listed on the FTL…' This respondent said, 'We are a nonprofit food bank distribution center. Does this Rule apply to us?' Another asked, 'We are a distribution center only, and we do not change or process the food while in our possession. How does this Rule apply to us?'

The Rule also makes provisions for facilities to apply for an exemption. Several companies, especially distributors in a similar situation to the one referenced above, asked, 'What will be the process to prove and maintain an exemption if one is allowed?' These types of questions about the applicability of the Traceability Rule run hand-in-hand with those directly related to enforcement in terms of who is required to do what,the type and intensity of enforcement to be expected, and how companies should prepare before the 2026 compliance dates.

Another theme that emerged from the enforcement questions was asking for help from FDA. Companies are eager for help in getting suppliers to understand and comply with the requirements of the Rule so that processors, especially smaller ones, are not put in the position of being responsible for educating several layers of their supply chain in compliance requirements of the Rule, or face penalties. If FDA implements strict levels of enforcement for suppliers and producers of end products, then end-product producers can be more confident that getting the data they need from their supply chain will be easier and the responsibility for education, awareness, and enforcement

> **"Many companies are looking for a high degree of outreach and education from FDA for everyone in the supply chain, so that all are aware of the Traceability Rule and understand its requirements."**

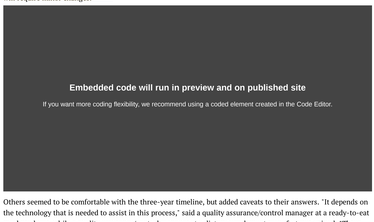
The second most-cited concern has to do with compliance requirements. This series of comments can be simplified to, 'What, specifically, needs to be done in my situation, and how do we get it done?' Many mentioned that without further clarity of all the steps required, it will be difficult to perform a gap analysis between current practices and Traceability Rule compliance. One processor wants to know, 'Are our current practices not sufficient enough to match some of the KDEs being maintained?' Another asked, 'What requirements for our suppliers are different from the requirements for our third-party auditors?'

The main topics within processors' remaining major concerns can be characterized as elements of the execution of their eventual plan, concerns about the complexity of the programs and recordkeeping needed, and important considerations on additional staffing and costs required to comply with the Traceability Rule.

Only 5 percent of processors said they had 'no concerns' about the Rule.

As anxiety-producing as these questions and concerns may sound, 87 percent of companies said that a three-year compliance timeframe was reasonable (Figure 5), with only 11 percent indicating 'maybe or not sure' on the timeframe. Of the 87 percent who agreed, many said that they believed they had many of the necessary pieces already in place. One vegetable processor mentioned, 'Three years is reasonable… most growers have already implemented the Rule.' An infant formula producer said, 'Yes, I believe we are already compliant; if anything, it

FIGURE 5. Is the Three-Year Compliance Period Reasonable?



Others seemed to be comfortable with the three-year timeline, but added caveats to their answers. 'It depends on the technology that is needed to assist in this process,' said a quality assurance/control manager at a ready-to-eat meal producer, while a quality assurance/control manager at a dietary supplement manufacturer opined, 'Three years is typically enough time to update a procedure.'

A food safety specialist at a fruit and vegetable processor was less convinced that the three-year compliance deadline was reasonable, saying that FDA will have a big role to play in the achievement of this deadline. 'I'm not sure,' he said. 'The FDA has not been clear about what is included in the final rule. They need to 'educate' before they regulate.' FDA should hold educational sessions that clearly lay out the expectations of the law.'

The April/May issue of *Food Safety Magazine* will include Part 2 of this investigation, where we will hear more from processors on the systems and processes they are currently using to track their supply chain and suppliers, and how they plan to adjust or upgrade their systems to address the added demands of the Traceability Rule. We look forward to bringing those perspectives to you in the next Food Safety Insights. ■

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***Bob Ferguson** is President of Strategic Consulting Inc. and can be reached at bobferguson8804@gmail.com or on Twitter at @GCI_Ferguson.*

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Why a Paradigm Shift is Needed in Food Safety Auditing

The future of food safety auditing will be different from what we know today, but the pace of change must be faster

By Marc Cwikowski and Tülay Kahraman, Co-Founders, World of Auditing

There will be no audits in the future. We mean as they are today.

We had a dream.

We heard someone say: "You can audit us at any time, and we'll be happy to show you why you can trust us. If you find issues we're not already taking care of, then we'll fix them forever and thank you."

Are we there yet?

We are facing unprecedented challenges. At the same time, the forces shaping the future offer many new opportunities to enhance the value that audits provide. The future of food safety auditing will be different from what we know today, but there are concerns that change needs to be faster.

Food safety auditing has progressed a great deal in the last three decades, but it is clear that it has yet to keep up with changing needs, expectations, and technological developments. Future audit approaches will need to change significantly to have a greater impact. The mindset must also shift. We must act now.

"If you want to know the future, look at the past," Albert Einstein once said.

The purpose of auditing and the driving force behind its development are both linked to trust. This has been the case since auditing began. Professional auditors have always been relied upon to address the needs of those seeking assurance about the actions or performance of others. It is the same with food safety auditing. It all boils down to trust.

Here is our experience in the food industry.

In the late 1980s, retail auditors visited manufacturing facilities to determine whether their organization would purchase products. That was a critical point for both the auditors and the plants. They were looking for objective evidence to confirm confidence in the processes and products. Plants were doing everything they could to demonstrate that the auditors should trust them. Both the pressure and the stakes were high.

Numerous audits were performed because each customer had its own audit program and checklists. Furthermore, auditors were returning, regardless of the previous audit result. Being good did not affect the frequency with which manufacturers were audited. There was no risk-based audit approach, but manufacturing plants learned a lot, which prompted continuous improvement.

No certified food safety management was in place at that time; therefore, no concept of formal internal auditing, as we know it today, existed. There was, however, a willingness to ensure that plants were ready for the customer audit when they arrived. The same was valid for regulatory inspections. It was all about demonstrating adherence to requirements and learning from the experience to improve.

Audits and inspections were highly focused on compliance, with incredibly detailed checklists. As they differed from one customer to the next, it was challenging to design and maintain a system that would satisfy everyone. It was not impossible, however.

Adopting a management system approach has been a game changer. The late-1980s creation and subsequent development of the ISO 9000 family of standards positively impacted the food and beverage industry. These standards enabled food and beverage companies to incorporate their food safety requirements and those of their external stakeholders. It also provided them with a solid foundation for implementing an internal auditing program and verifying the system's effectiveness. Certification was primarily used to demonstrate trustworthiness to others. ISO 22000 came later. This auditable standard, first published in 2005, was outcome-focused, providing requirements for any organization in the food industry to help improve overall food safety performance.

High-profile food recalls in the late 1990s prompted a shift. In 2000, the Global Food Safety Initiative (GFSI) was established in response to major food safety issues and recalls. Consumer trust was eroding, and the food industry recognized the importance of working together to improve food safety. Audit fatigue was also a reality. Since food safety standards were not harmonized, redundant inspections and audits were the norm. This was both costly and time-consuming for all, including buyers and suppliers. The first draft of benchmarking requirements was published in 2001, and a pivotal moment occurred in 2007 when seven major retailers announced their acceptance of GFSI-benchmarked certification programs.

"Organizations can demonstrate their ability to be trusted partners in the supply chain by demonstrating compliance through third-party audits and certification."

How are We Doing Today?

As we write this, the number of audits against GFSI-recognized programs is increasing, while multiple certification and customer audits in addition to GFSI are common. Undoubtedly, the coalition's and all stakeholders' efforts helped and will continue to help improve food safety. Still, the current food safety audit context appears to be heterogeneous, with room for improvement. Several types of audits coexist, each with its characteristics and value. They do sometimes overlap.

First-party audits are performed to self-assess the company's food safety management system and identify areas for improvement. These types of audits are carried out regularly to ensure food safety compliance and readiness for external audits. They are, by design, a fantastic opportunity to be honest and look in the mirror. Are they delivering the total value they could? These audits offer significant opportunity.

Second-party audits are performed by or on behalf of a company to other related businesses, such as its suppliers. They are used, for example, to assess the suitability of a new or existing supplier based on the effectiveness of their food safety management systems. They typically use a specific set of food safety requirements from the company, which may differ from or be in addition to those implemented by the supplier. They appear to be gaining popularity.

External auditors from food safety auditing firms perform third-party audits to assess a company's food safety management system. This type of audit is frequently used to obtain certification. These audits numbers are still growing.

Where Do Opportunities Exist?

Food safety audits can provide enormous benefits when adequately designed and implemented, and the authors work with organizations that have done so. We also observe companies outside the food and beverage industry leading the way in making the most of their audits.

Consider the definition of value as the ratio of benefit to cost. In this case, first-party audits are well-positioned to maximize it, drive continuous improvement, and demonstrate that the food safety management system can be trusted. However, the authors' experience with first-party audits in the food and beverage industry indicates that opportunities exist to maximize their value. We discovered that some other sectors are doing much better in this regard.

Second-party audits are widely performed, and their importance is twofold. They are an essential component of a supplier management program that assists businesses in identifying and managing risks in their supply chain. They also promote continuous improvement at the supplier's sites when embedded correctly in the plan-do-check-act (PDCA) cycle on the receiving side. Companies that use second-party audits where they matter most in their supply chain reap significant benefits.

Organizations can demonstrate their ability to be trusted partners in the supply chain by demonstrating compliance through third-party audits and certification. It is vital. This is where GFSI-recognized certification programs have played an essential role over the last two decades. Certification, however, appears to have turned into a "license to operate" in the food supply chain. While facilitating market acceptance, it must deliver the value it could and should, especially to mature businesses.

Despite these various types of audits, food safety issues continue to occur, risks remain undiscovered, and businesses struggle with repeating problems. The current auditing model is very retrospective. If the aviation industry's safety performance were comparable to that of the food industry, one would think twice before boarding a flight. How are they handling things?

In a typical year, approximately 130,000 flights per day take off and land without incident. Furthermore, long-term accident trends confirm that aviation is getting safer, and the safer aviation becomes, the more challenging it is to drive further improvement. There has been enormous safety progress in the last two decades thanks to effective aviation safety management systems, and auditing has played (and continues to play) a critical role.

Meanwhile, according to the Food and Agriculture Organization of the United Nations (FAO), an estimated 600 million people—almost one in ten people in the world—fall ill after eating contaminated food, and 420,000 die yearly. Despite the implementation of food safety management systems, audits, and certifications, national authorities reported more than double the number of recalls and border rejections in 2019 compared to 2009.

What can we learn about food safety auditing from the aviation industry?

In 2003, the International Air Transport Association (IATA) launched the IATA Operational Safety Audit (IOSA) program as an evaluation system designed to assess an airline's operational management and control systems. It was established to address the airline industry's need for globally harmonized operating safety standards. Before implementing IOSA, airlines evaluated one another's ability to provide safe operations. The audit standards were inconsistent and varied. Have you heard of anything like this before?

IOSA is an essential part of the industry's efforts to improve aviation safety, and it is now widely regarded as the gold standard in airline auditing. It has two primary objectives. The first goal is to enhance airline operational safety through a globally accepted audit program based on internationally harmonized standards. The second goal is to increase airline efficiency by eliminating redundant audits. It is all about continuous improvement—mission accomplishment in all aspects, with data to back it up.

In today's dynamic environment, IATA is evolving IOSA to focus on potential safety risks, rather than a 'one-size-fits-all' approach. Introducing a risk-based approach will tailor the audit scope for each airline. The new method also includes a maturity assessment of the airline's safety critical systems and programs. IATA believes that focusing on relevant safety risks while maintaining a baseline will improve audit effectiveness and contribute to the aviation industry's goal of reducing accident rates.

When compared to the food industry, several characteristics are inspiring: one standard in safety auditing, the critical role of internal audits, auditors and auditors being valued for their role in continuous improvement, a focus on root cause analysis and problem-solving, digitalization, and a move to risk-based and predictive approaches.

The frame of the audit processes, from preparation, execution, closure, and follow-up, is similar in the food and aviation industries. Still, the way, the depth, and the rigor at which each component is implemented make the difference. Our food and beverage industry requires a paradigm shift. It is about our food safety audits' why, how, and what. It is also about mindset, and this is critical given what is on the horizon.

What Challenges are On the Horizon?

As we stated at the outset of this article, we are facing unprecedented challenges. The number of drivers for those is quite significant. It is vital for food and beverage companies to understand the driving forces and their implications to take a position.

Climate change has a severe impact on many other aspects, including the safety of food. The change in temperature results in heavy rainfalls, hurricanes, and floods, altering the geographic distribution and nature of pathogens. Food companies are facing a higher number of outbreaks due to *Salmonella* spp., *Campylobacter* spp., *Listeria* spp., *Escherichia coli*, as well as mycotoxins, and research indicates a correlation with climate change.

The impact is not limited to biological contaminants. The soil is abused with harsh climate conditions, which impacts the type and concentration of chemical contaminants (e.g., heavy metals, pesticides). The nutritional content and stability of crops are being damaged while the world population continues to increase at a rapid pace, resulting in high demand for food. On the other hand, increased food supply is one of the primary sources of high greenhouse gas emissions, degraded ecosystems, and water scarcity. A substantial number of studies and efforts are underway to understand and control the impacts of climate change, keeping in mind that some are irreversible.

Globalization of the food supply chains also facilitates an increase in foodborne hazards as local incidents become international outbreaks. As one of the major drivers, globalization affects population movements and the development of new economic models, which then shape consumer preferences and food consumption patterns. Buying decisions, for example, are now made on a couple of additional criteria compared to the past. Consumers are looking for a healthier diet and considering sustainable options. Plant-based and cell-based production technologies are on the rise. As a result of using new supply sources for new processing technologies, new allergens (i.e., due to more frequent use of peas and legumes) and new pathogens are entering our catalog of food safety hazards. It is important to note that no clear regulatory frameworks exist for some of these novel foods, and debates are on the table as some people consider the new ways of production as an attack against the cultural element of food.

On the behavioral side, we see a clear shift from traditional shopping to online purchases, which accelerated more with the onset of the COVID-19 pandemic. Economic conditions and isolated living encouraged people to consume food more often at home, which changes how the food is produced, packed, and marketed—e.g., the increasing popularity of home-delivered meal kits. This results in additional complexities regarding food delivery and services while introducing new safety concerns such as cross-contamination, mislabeling, and authenticity in a space where regulations do not exist or governance is not as strong as for plant-manufactured food items.

Is the current setup of food safety auditing capable of dealing with these challenges on the horizon?

"Food and beverage companies with a significant presence in the future will be those who plan from today. This will require an entire overhaul to anticipate future food safety risks and opportunities."

A Vision for the Future

Surely many of us know Eric Yuan, the entrepreneur behind Zoom Communications. Company origins can be traced back to 1987, when Eric's then-girlfriend and future wife was attending a university located more than ten hours away by train. He had the insight to envision a product and business that would facilitate video conferencing and provide user-friendly support. Eric Yuan indeed designed the future years ago with this foresight.

Food and beverage companies with a significant presence in the future will be those who plan from today. This will require an entire overhaul to anticipate future food safety risks and opportunities. We observe that the agricultural, pharmaceutical, and food industries are struggling with similar challenges, and we have been discussing those internally for some time, with limited progress.

Recent changes and trends blurred the traditional borders between these industries, and end-to-end solutions are needed now more than ever. An integrated, cross-industrial approach is required to understand the scope and magnitude of the associated risks and the proper ways to manage them. Looking even further, and learning from other industries advanced in managing risks (such as aviation), would help a great deal. Benchmarking should be the buzzword for any possible occasion.

So far, the food and beverage industry has generated massive data about food safety performance, and audits have played a significant role in this. For some time, we have been observing a shift from compliance-based audits to risk-based audits in the pursuit of greater value. Areas for improvement remain, as incidents do happen. A change is needed from reactive to proactive in understanding how companies manage risks, what tools they use to predict the future, and what measures they put in place to manage those risks. The future of food safety auditing will be as good as we design it to be.

What are the Possible Scenarios for the Future?

We predict that the frame of the auditing process will remain the same, while the methods and approach to managing those processes will evolve. The new approach should consider the following aspects for the design:

- Taking a systematic, medium- to long-term view of the future (horizon scanning) and adapting the process and resources based on emerging hazards and risks (risk-based approach)
- Understanding the impact of globalization and economic conditions on the overall performance of food and beverage companies and their supply chains
- Navigating through changing government policies and regulations (and sometimes in the absence of those).

It is also crucial to look at different types of audits (first-party, second-party, and third-party audits coexist, and some overlaps exist) and the value they bring to the food and beverage business. A need may arise to redesign the entire auditing frame based on the outcome of this holistic evaluation. While doing so, the potential role and impact of the internal audits within the operating units (manufacturing plants, distribution centers, support offices) should also be considered.

During COVID-19, we have observed that some companies have identified the need to empower their internal auditors on manufacturing sites more, as they had to rely on the internal audit reports from the factories for some time period. While conducting remote audits during this time, they narrowed the focus to the effectiveness of the internal audit program and the actions taken to address the issues. With this new understanding, they have changed their approach to train, coach, and develop internal auditors onsite.

A solid internal auditing program at the site level will help organizations identify immediate and future risks and opportunities faster and, in most cases, *better* when the bias is removed. Food and beverage companies should consider smart ways to strengthen the internal audit program execution at the field level. This is a critical change management and will require substantial effort for the cultural transformation.

When we talk about internal audits, it is almost impossible not to mention the corrective and preventive action program (CAPA). CAPA supports continuous improvement and is very much dependent on the organization's capability to identify the problems and the root causes of those issues. Our experience is that the CAPA programs are often not supported by a robust internal audit program, and the organization is not able to identify the underlying root causes, or conflicting goals (e.g., water reduction goals vs. cleaning effectiveness) are making it difficult to choose the right option. In most cases, the result is repeat findings (in some cases, with a more significant magnitude) that lead to fatigue in the workforce and deteriorate the health of the food safety management system. Strengthening the CAPA follow-up as part of the overall auditing process and supporting operations to improve their skills in managing the program are key for future success.

Use of Technology

Emerging technologies will be critical in the future to support food safety auditing. Remote auditing technologies underwent a testing period during the pandemic, and some are effective when used as part of a hybrid approach. Artificial intelligence (AI) is presently and will be widely utilized to analyze data and determine the risks and opportunities. Machine learning, a subset of AI, is already assisting humans by generating educated and improved decisions and individualized suggestions based on the algorithms evaluated. Deep learning can examine unstructured data such as emails, social media, and reports. Information technology is being utilized to assist auditors for reporting purposes. Data mining is highly promoted for use in integrity check programs of certification bodies, as well as audit organizations. We should be expecting more to come, and mainly for the better.

In deploying these technologies, there remains a challenge that is often overlooked. Auditing involves a good deal of human judgment. Big data that the audit organizations and auditors will be analyzing can become overwhelming and create cognitive limitations. We do see a need for additional research to determine the optimal method for navigating through large data sets.

"The future of food safety auditing requires not only talent, but also the necessary experience to gauge the risks linked to business strategies."

The Most Critical Element of Auditing

It is vital to remember that technology is only an enabler. The future of auditing is mostly about people. Having the right people, the right skills, and the right approach are key to success. How can we define the future of food safety auditors beyond industry-specific technical expertise?

We know that the food and beverage industry has been struggling to find the right talent for some time. The future is demanding even more. Future auditors of food safety should possess a high level of learning agility. This is essential for them to understand industry dynamics, the business they work for, strategies for the coming months and years, risks and opportunities that the future holds, and their role in supporting the management of those risks. Auditors must be skilled at communicating with individuals at various organizational levels. They must act like an advisor taking the auditee through the process to excel. They must be tech-savvy to utilize technological tools in the execution of audits.

The way we look at the auditing profession requires a nudge. We observe that food safety auditing roles are relatively junior in the internal audit organizations of food and beverage companies and are positioned as a "stepping stone" for more senior roles. In a way, audit organizations are creating a pool for future talent. This framing makes it difficult to attract more senior people in the discussions with the auditees, including some senior managers. This is a significant load to place on their young shoulders. The situation is not different for certification bodies, as there are always cost pressures on their services. The risk exists of auditors with insufficient experience making their way into the system due to tight margins in the market.

While designing the future of food safety auditing, a substantial amount of effort and thinking should go into the future role of the different stakeholders: auditees, business partners, boards of directors, and everyone else who receives the audit results and uses them for the greater good. They must roll up their sleeves to assist audit organizations and auditors in making the most out of it. This should be accomplished by proactively expressing their needs and expectations, helping the auditors and audit organizations make a better judgment, or deploying some of their critical resources in the service of the entire company through auditing. We see that most of the heat and pressure go to the audit organizations to increase the value of audits. The other side of the table also influences the quality of the outcome, and must be held accountable. While designing the roles and responsibilities, efforts should be made to change the perception of auditing from a source of cost and torture to a value generator.

We have a dream.

We hear someone say: "You can audit us at any time, and we'll be happy to show you why you can trust us. If you find issues we're not already taking care of, then we'll fix them forever and thank you."

How can we get there?

We believe it will happen only with the collaborative efforts of food and beverage industry experts. The first few steps are to:

- Understand and remove overlaps between different types of audits to make them contribute to one another
- Work with all stakeholders involved (i.e., universities, certification bodies, and peer companies) to develop the right skills for the auditors of the future.

We will get there, together. ■

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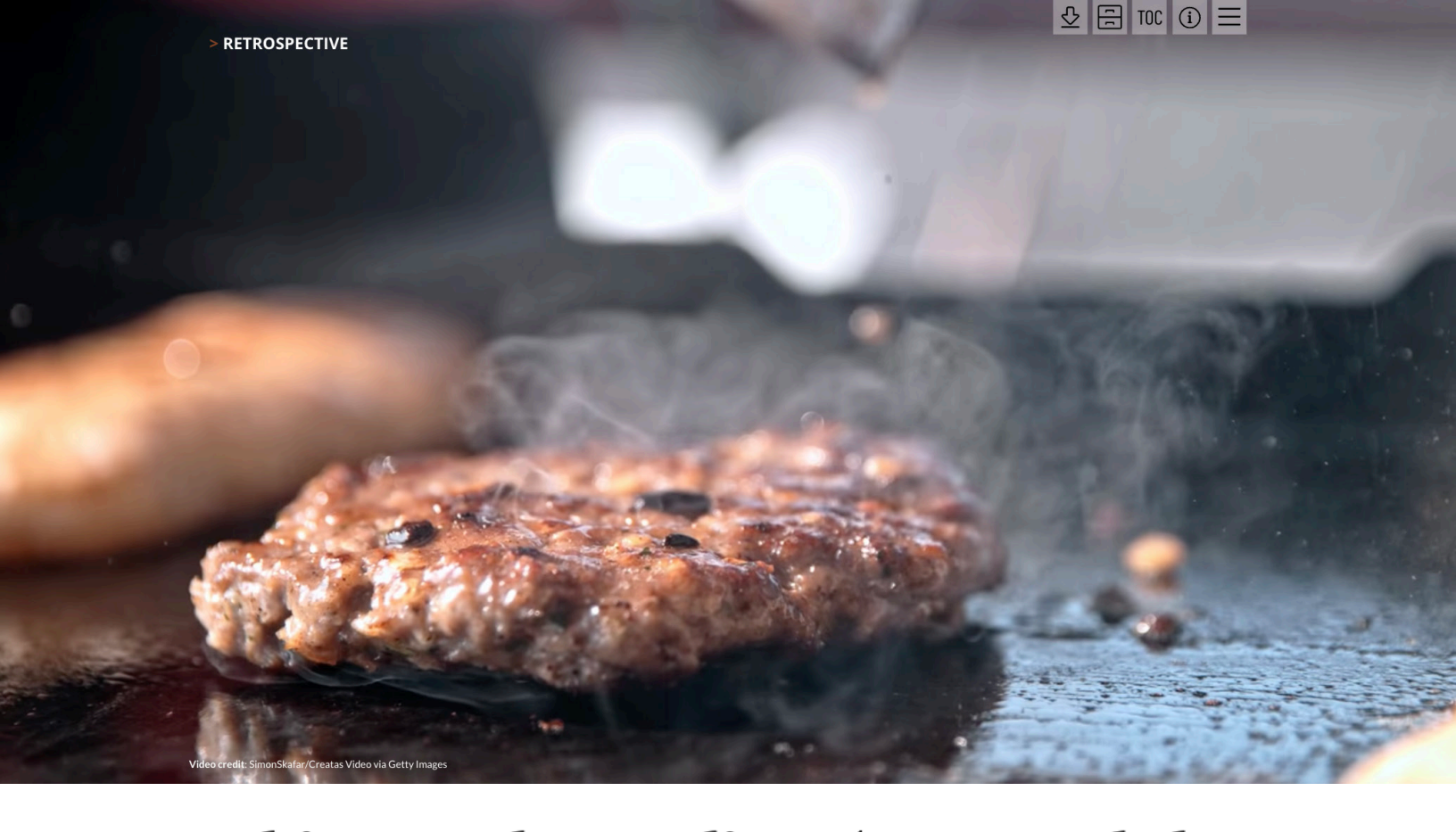

Looking Back: *E.coli* O157:H7 and the Legacy of Dr. David Theno

The story of the 1992–1993 Jack in the Box outbreak is well documented, but how E. coli O157:H7 first showed up on the radar is less known

By Andrew Kesler, Corporate Director of Supplier Compliance

Thirty years ago in January saw the beginning of what became known as "The Crisis" at Jack in the Box restaurants, when hundreds of customers became seriously ill after eating hamburgers containing *Escherichia coli* O157:H7. This illness outbreak—at the time, the largest in U.S. history—would claim four young lives, leave many others with lifelong health impairments, sicken over 700 people, and nearly ruin Foodmaker Inc., the parent company of Jack in the Box.

Two years prior to this outbreak, in 1991, I spent my first Thanksgiving away from home at a Jack in the Box restaurant in Lompoc, California. At the time, I had no idea that Jack in the Box would become a defining part of my career in food safety or that I would ever have a career in "food safety." I would later join the quality assurance team at Jack in the Box, led by the late Dr. David Theno, a prominent food safety and process control consultant who was hired by Foodmaker to figure out why the outbreak occurred and to put systems in place to prevent another one from happening.

The story of this seminal illness outbreak is well documented, but how *E. coli* O157:H7, the deadly organism responsible for the 1992–1993 Jack in the Box outbreak, first showed up on the radar is less known. The story begins a decade earlier, in 1982, with another, much larger, fast food restaurant chain. It is important to examine this earlier outbreak (which was technically two outbreaks) to understand why the aftermath of the Jack in the Box outbreak was much different, as well as how it propelled huge changes in the meat industry and within large restaurant chains. The entire food industry became much stronger actions and regulations borne from our collective journey with pathogenic *E. coli*.

Forty Years Ago

The 1982 *E. coli* outbreaks are not well known or discussed in nearly any historical account of *E. coli* O157:H7. The name of the restaurant chain involved is rarely associated with the outbreaks in the same way that Jack in the Box is forever linked to the 1992–1993 outbreak. In 2012, Bill Marler, the attorney who represented many of the victims of the Jack in the Box outbreak asked (rhetorically) on his blog: "What if, in 1982, McDonald's had been named as the source of the 47 sickened by *E. coli* O157:H7-tainted hamburger in two states?"[1] Would the Jack in the Box outbreak have occurred ten years later? That is a nearly impossible question to answer, but the 1982 outbreaks did not make the national news, nor did they prompt the collective changes in food safety spurred by the Jack in the Box outbreak, in which four young children died.

On March 24, 1983, the *New England Journal of Medicine* published the article, "Hemorrhagic Colitis Associated with a Rare *Escherichia Coli* Serotype."[2] The article summarizes the investigation results from two outbreaks, one in Michigan and one in Oregon, which sickened "at least" 47 people in early 1982. The common food in the outbreaks was hamburger with three common ingredients from a single fast-food chain—beef patty, pickles, and rehydrated onions. While the report did not name the restaurant associated with the outbreak, only one fast-food chain at the time had restaurants in both Michigan and Oregon, cooked hamburger patties on flat grills, and used rehydrated onions.

One brief news article about the outbreaks, probably buried on the back pages of *The Washington Post*, was published on October 9, 1982. It linked McDonald's to what was then a "rare intestinal illness... which may be linked to undercooked hamburgers." Cristine Russell, writing for *The Washington Post*, remarked that the McDonald's home office in Oak Brook, Illinois "...contended that the link with its hamburgers might be a statistical anomaly and said that the company's required cooking procedures 'ensure product safety.'"[3] In defense, McDonald's Vice Chairman, Edward Schmitt, made remarks about the small number of illnesses as "isolated incidents." He further remarked that the chain had served almost two billion burgers since the illnesses occurred. In this context, with little known about *E. coli*'s ability to make humans sick (and kill them), it is understandable to characterize this event as an "anomaly."

Although McDonald's publicly declared the outbreaks to be an anomaly, the company took action to investigate the microorganism and new cooking technologies to combat it—a very early example of large foodservice companies sponsoring and promoting significant food safety research in partnership with government and industry. After the 1982 outbreaks, McDonald's hired then-University of Wisconsin microbiology professor Dr. Michael Doyle, who recommended new clamshell grills (among other actions) that would cook patties simultaneously on both sides and not open until the cook time was completed. The cook times and temperatures were researched thoroughly to ensure that harmful microorganisms were destroyed during the cooking process. Side note: I was an assistant manager at a McDonald's restaurant in the late 1980s and helped install the new clamshell grills. It would be more than 30 years before I connected the dots behind why we switched to this equipment. At the time, I assumed it was to cook the patties faster and increase "speed of service."

Still, the 1982 incident remained an obscure, back-page news article, and the controls implemented to ensure product safety were intended to solve the problem primarily through control steps in the restaurants. It would be an entirely different outcome ten years later, after four children died from undercooked hamburgers served by the nation's fifth-largest fast-food chain. The news went national with the Jack in the Box logo all over it, which got the attention of the public, the industry, the regulators, and, most importantly, Washington, D.C. There was no keeping the Jack inside this box.

> **"Dave Theno's goal was to give the leadership team specific metrics to monitor as an indicator of the health of their food safety program, so that they could take immediate action if the system went out of control."**

Thirty Years Ago

Dave Theno told the story many times. To remind him of whom he actually worked for, regardless of the company logo on his paycheck, he carried in his wallet a picture of six-year-old Lauren Rudolph. He often showed the picture to people when explaining why he recommended a particular course of action to protect public health. "Lauren is who we are protecting. Lauren, and the children she represents, is who I report to," he would say. She was the first victim of the Jack in the Box outbreak, and Dave got to know her family well through the ordeal.

The story of "The Crisis," as it came to be known at Foodmaker, was expertly researched and told by Jeff Benedict in his 2011 book, *Poisoned*.[4] The major parts of the outbreak had been explained before, but what the uncomfortable narrative teaches is how hemolytic uremic syndrome (HUS), an infection of the digestive tract caused by *E. coli* O157:H7, destroys the red blood cells in the body, causing extreme pain in the kidneys and other organs as they begin to fail. That such young children could die such painful deaths—just from eating a hamburger—was unimaginable to me. Riley Detwiler, one of the four young victims, did not even eat a hamburger. He merely came into contact with another child at a daycare center who had eaten contaminated beef—a testament to how virulent *E. coli* O157:H7 can be, even spreading through cross-contact among people.

By early 1993, the outbreak had become national news, with a newly elected president calling the parents of the victims and promising to do more to ensure safe food. Regulators and industry had become more willing to accept changes in how food was inspected. The relentless national media attention, combined with civil litigation resulting in multimillion-dollar settlements for the victims, created an environment that demanded significant change—on the part of industry and regulators.

The course of action Dave embarked on when he arrived at Foodmaker—first as a consultant, and then full-time as a Vice President—was to determine where in the process, from farm to fork, controls could be implemented and measured to ensure safe hamburgers. His goal was to give the leadership team specific metrics to monitor as an indicator of the health of their food safety program, so that they could take immediate action if the system went out of control.

Dave realized that fully cooking the hamburgers solved only half the problem. Knowing that the pathogenic organism can be transferred through bare-hand contact required an additional mitigation step to solve the other half of the problem. He implemented a "no bare-hand contact" rule with raw hamburger patties, which was unheard of at the time for any large restaurant chain. Training grill employees to use tongs, rather than their hands, to separate the frozen patties and then place them on the grill was no small feat, especially when it was common to place up to 12 patties on the grill at the same time.

In the restaurants, Dave implemented a mandatory "final flip and visual check" of each patty before pulling it off the grill to make sure the patty was not pink after the scheduled cooking time. (Unlike McDonald's, which had plenty of cash to invest in clamshell grills, Foodmaker did not have such capital available at the time. It was uncertain if the company would even survive.) The combination of checking each patty and monitoring the temperatures of the grill surface and the internal patty several times each day ensured the cooking process was continuously in control.

"No bare-hand contact" and the "final flip and visual check" became the fundamental critical control points in what was the first HACCP program created for a restaurant; and these two steps were observed and documented by the restaurant's management several times throughout the day. Procedures were also implemented to verify the cooking processes by measuring the temperature of the cooked patties several times per day. This became another critical control point in the restaurant HACCP program. Compliance with these steps in the process, along with many others, was now measured and became a metric for Jack in the Box's operations teams to monitor the health of their restaurant chain's food safety system.

Dave just as quickly turned his attention to the supply of hamburger patties, taking a methodical approach to implementing HACCP from feedlots and slaughter to the ground beef operations that produced the hamburger patties. Few "grinding operations" at the time were willing to implement a new microbial monitoring program to test both the incoming meat and the raw ground hamburger patties for *E. coli* O157:H7. However, Texas American and CTI Foods both signed on to adopt the new system; and by implementing the program, the industry as a whole learned much more about how pathogenic *E. coli* enters the supply and production system.

Over time, additional slaughter and fabrication mitigation steps were employed to reduce microbial loads. While testing was used to exclude contaminated supply, the intention of the testing program was to learn and make continuous improvements to the controls within the process. Fundamental to the success of the testing program was defining and tracking "lots" within the process to allow for traceability and proper rotation. Microbial testing results of the beef supply became a defining metric for Jack in the Box's leadership team.

One of the most meaningful actions Dave took was to openly share the testing program and controls with anyone in industry who was interested, including competing restaurant chains. He firmly believed that there was no competitive advantage in food safety. We have learned over time that an illness outbreak from one company can have negative impacts on an entire food industry segment—peanut butter, tomatoes, cantaloupes, and lettuce, to name a few.

Quality and Process Control through HACCP

Before joining Jack in the Box, Dave Theno had already pioneered the use of HACCP and its concepts to achieve microbial reduction through "process control." Before Jack in the Box, Dave had built a very successful consulting business working with clients who wanted to implement process control through HACCP in their organizations. At the start of his career, he demonstrated that by identifying and monitoring key steps within the poultry slaughter process, the rate of *Salmonella* contamination in chilled carcasses could be reduced from 35 percent to around 1–2 percent. Even for processes where there is no "kill step," such as slaughter, identifying the key steps within the process that can be controlled and measured, and then measuring them, helps achieve microbial reduction through data visibility and continuous process improvement. This is exactly what happened as a result of the microbial testing that was implemented for Jack in the Box's ground beef supply. The data allowed for examination of processes further back in the supply chain and identified areas where additional microbiological control technologies would help reduce the overall level of *E. coli*. Consequently, over the three decades since the program was implemented, the U.S. ground beef supply has far less exposure to pathogenic *E. coli*, and illnesses associated with ground beef have been substantially reduced.

In the 1980s and early 1990s, not everyone at the U.S. Department of Agriculture (USDA) or in the industry was a proponent of controlling processes through the use of HACCP, even though the National Aeronautics and Space Administration (NASA) had successfully used it to ensure safe food for their astronauts in space. The traditional process of government inspectors visually inspecting and stamping every animal carcass to declare safety was entrenched and viewed by many in the meat industry and government as successful. After all, the HACCP detractors reasoned, the consumer was surely responsible enough to know to cook raw meat thoroughly before eating it. The HACCP proponents would correctly point out, however, that pathogenic microbial contamination cannot be observed through traditional visual inspection. A new system of controls during the slaughter and manufacturing processes was needed to enhance visual inspection. The Jack in the Box outbreak softened attitudes toward HACCP, creating a window of opportunity for change, and in July 1996, a final rule—*Pathogen Reduction; Hazard Analysis and Critical Control Points (HACCP) Systems*—was published in the Federal Register.[5] It became known as USDA's "Mega Reg." Timothy Lytton's 2019 book, *Outbreak*, provides additional insight into the history behind the development of this regulation.[6]

In 1996, I had just started my career in the food manufacturing industry as Quality and Process Control Engineer for Hormel Foods. At the time, Hormel used a Total Quality Control program in its manufacturing plants to ensure that its processes were in control and producing safe, consistent product. Each step of the process was clearly defined, and the program outlined how each step in the process was to be monitored, and by whom. Each page of the 60-plus-page document was approved and stamped by USDA's Food Safety and Inspection Service (FSIS). Any changes, no matter how minor, needed to be reviewed and approved by USDA. Thus, USDA approved the program under which the plant operated, and routinely inspected the approved individual activities required by the program, essentially serving as quality control. If the program required pulling 60 cans of chili after the cooking process and incubating them, the USDA inspector would create a Process Deficiency Report (the predecessor of today's Noncompliance Reports) if they counted only 59 in the incubator. The role of Quality and Process Control Engineers at Hormel was to ensure that the processes were continuously in control and to bring them back into control when necessary. The USDA inspector's role was to inspect the plant and its processes and notify plant management when deficiencies in approved processes were observed.

The implementation of HACCP largely turned the development and monitoring of process control systems over to the manufacturing plants, theoretically reducing the burden on regulators. The plants developed their control programs using the principles of HACCP, and USDA's new role was to ensure that the plant was executing its HACCP *system*—which was more of a quality assurance vs. quality control approach. At the time, I was tasked with writing the new plans and implementing them at the plant level. For the companies that employed Total Quality Control plans, the switch to HACCP was relatively easy since the controls in the process were already defined. For many smaller companies, however, implementing HACCP was a long and difficult journey.

The Jack in the Box outbreak propelled an entire industry into a new way of monitoring process controls within manufacturing plants and shifted USDA's role in food manufacturing from control to oversight, a system that continues today.

> **"Every process, even processes without steps to reduce or eliminate harmful bacteria, can be measured at key steps. That measurement data can be used to monitor process control and continuous process improvement."**

Thirty Years Later

The story of *E. coli* O157:H7 cannot be told without discussing Dr. Dave Theno and his contributions to the safety of our nation's food supply.

The root causes of the Jack in the Box outbreak largely shaped many of Dave's philosophies about food safety. Manage risk as far back in the supply chain as possible, implement microbiological testing programs when the data can be meaningful in driving continuous process improvement, design solid processes, and ensure they are in control from "farm to fork." The learnings from his early career work in process control measurement remain universal. Every process, even processes without steps to reduce or eliminate harmful bacteria, can be measured at key steps. That measurement data can be used to monitor process control and continuous process improvement.

Lastly, "you get what you demonstrate you want." This means that, as a leader, your employees will deliver on what is important to you—not necessarily what you *say*, but what you *demonstrate* is important through your actions, what you measure, and how you publicly acknowledge and reward employee performance. Those actions are important concepts in today's ongoing discussion about creating food safety cultures within organizations. As an operations vice president, if your first question to your plant management team is about order fill rates, production line efficiencies, or labor costs, then you have clearly established what is first and foremost on your mind. If your first question is about environmental monitoring results, critical control point compliance, or reported customer complaints, then you are demonstrating that food safety is your top priority. Plant management is able to keep track of all these metrics, of course, but the order in which you ask about them communicates your priorities as leader. Those priorities will become your team's priorities.

At a memorial service for Dave Theno in 2016, Bill Marler, the attorney who sued Foodmaker and won substantial settlements on behalf of his clients, spoke about Dave and his legacy. For any other person, it might have been odd to have the attorney who sued the company you worked for attend your memorial service, but not so for Dave. In the years following the outbreak, he maintained open communication with Bill Marler. Not in the sense of "keep your enemies close," but because their collective goal, even working on opposite sides of the fence, was the same: make the food supply as safe as it can be. Dave truly lived by his words that he was working for Lauren Rudolph and everyone she represented.

Dave was a well-respected thought leader in food safety, known by regulators, industry, and litigation attorneys alike. He trained a generation of food safety leaders to continue working toward a safer food supply by applying science and common sense to process control and decision-making through data analysis. His larger-than-life personality also helped elevate the role and visibility of food safety as a profession. When I began my career in food manufacturing in the 1990s, it was in the quality control department; food safety departments did not yet exist. Today, we continue to see more food manufacturers with a dedicated, experienced executive to lead an independent food safety function. The most progressive companies have this position on the top line of their organizational chart—along with sales, marketing, operations, research and development, supply chain, human resources, legal, and finance. The role is not buried beneath someone else's responsibilities, such as operations or supply chain.

For those of us in the business of making and serving food for human consumption (and especially those of us with "food safety" in our job titles), we should all carry a picture of Lauren Rudolph as a reminder of whom we ultimately work for and represent. Had she not eaten a hamburger, Lauren would have turned 37 this year; and Riley Detwiler, who did not eat a hamburger but died anyway, would have turned 32. ■

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***Andrew Kesler** worked for Dr. David Theno at Jack in the Box, and later as part of Dave's food safety consulting company, Gray Dog Partners, which he founded with his wife, Jill, after retiring from Jack in the Box as Chief Food Safety Officer. Dave's life work was food safety, which he expertly pursued to the very end. Andrew Kesler serves as Corporate Director of Supplier Compliance for America's leading producer of salads and fresh, healthy foods. Previously, he managed supplier food safety programs for McDonald's, Jack in the Box, and Qdoba restaurants. He also provided supply management support to Subway and other clients as part of Dave Theno's Gray Dog Partners food safety consulting team. Mr. Kesler began his career in food manufacturing at Hormel Foods after serving in the U.S. Air Force.*

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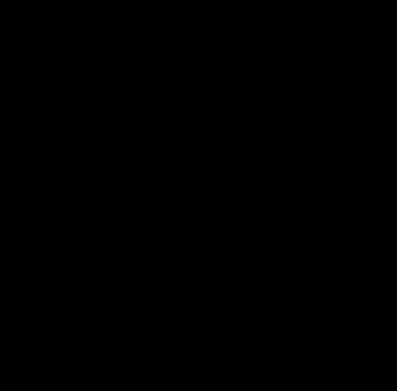

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Reducing Food Safety Risks in Meal Kits

In the lack of specific regulations, businesses that are involved in meal kits have a responsibility to minimize food safety risks

By Kelsey Jones, M.P.H., Environmental Health and Knowledge Translation Scientist, National Collaborating Centre for Environmental Health, Public Health Agency of Canada

Consumers are increasingly looking for convenient services[1] that help them plan and prepare delicious and healthy meals. Meal kits are one example of a service that has risen to meet this need, from their introduction in Sweden in 2007 to the present, where over 150 companies offer meal kits in the U.S. alone.[2] Consumers report that portion control, reduced food waste, a variety of food options, more meaningful family meal times, and the use of local food are key benefits of using meal kits.[2] Consumers were also drawn to meal kits in the face of restaurant closures during the height of the COVID-19 pandemic.

Meal kits use a direct-to-consumer model of delivering perishable, pre-measured ingredients for pre-selected recipes that are then used to prepare and cook meals at home. Meal kits are likely to contain a variety of foods that, in the absence of proper refrigeration, present a high risk for bacterial growth, such as raw meat products, eggs, and dairy. Other ingredients, such as raw produce, may be contaminated by pathogenic bacteria at the source facility or are subject to cross-contamination during processing alongside raw meat ingredients. Meal kit manufacturers also often repackage ingredients into plain or branded packaging, which can result in the consumption of unexpected ingredients or allergens. The combination of these considerations is unique to meal kits and creates unique applications with regard to food safety.

Meal Kit Recalls and Outbreaks

Meal kits have been involved in several food safety recalls around the world. Not all of these recalls have resulted in illnesses confirmed to be connected to the recall, including a 2018 recall of raw ground beef used in a meal kit due to the detection of *E. coli*,[3] and *Salmonella* detected in a meal kit ingredient containing red chili in 2019.[3] However, outbreaks of foodborne illness have also been traced back to meal kits, including 268 people falling ill in 2019 due to *Clostridium perfringens* that was traced back to a ready-to-heat minced meat sauce distributed through a meal kit in Denmark,[4] and a 2021 *Salmonella* outbreak that affected over 600 people in the U.S. due to contaminated onions[5] that were used in multiple meal kit brands and sold independently.

More recently, in 2022, raw ground beef that was distributed through meal kits was identified as the probable source of an *E. coli* outbreak that caused illness in seven people in the U.S.[6] Another meal kit product, a frozen package called 'French Lentil + Leek Crumble,' was linked to nearly 500 reported cases of gastrointestinal illness and impaired liver function.[7] While the cause of this outbreak is unknown, preliminary investigations have suggested that tara flour used in this product was the source of the adverse health outcomes.[8]

Regulation and Oversight

It is evident that meal kits have the potential to, and have, caused outbreaks of foodborne illness. However, as the widespread use of meal kits is relatively new, regulations and oversight have not kept up in many jurisdictions. In the lack of specific regulations, businesses that are involved in meal kits have a responsibility to minimize food safety risks. While businesses must abide by applicable laws and regulations in their jurisdiction, some additional best practices are more tailored to the unique risks present in meal kit operations. One such example is the guidance document prepared by the Conference for Food Protection for direct-to-consumer and third-party delivery food services.[11] This extensive document contains best practices for the prevention of biological, physical, and chemical contamination and discusses risk assessment, preventive controls, validation and verification procedures, packaging, temperature control, storage, and recalls.

Food safety risks can also be managed within a Hazard Analysis and Critical Control Points (HACCP)-based approach that evaluates the food safety risks throughout the lifecycle of the product and developing control points at each step of the process that reduce those risks. The following section of this article discusses some best practices that can be included in a HACCP-based food safety plan aimed at reducing risks specific to meal kits.

A HACCP Approach to Meal Kit Safety

While variation exists in manufacturing processes between meal kit services, most have similar steps involved including ingredient sourcing, food processing, food packaging and labeling, storage, transportation, and consumer handling. Each of these stages should be included in a HACCP-based food safety plan.

While other hazards may be present and need to be accounted for, the main risks to food safety that require particular attention in the case of meal kits include cross-contamination, temperature control, and allergens.

"Meal kits often contain ingredients in the same box that are to be cooked and eaten raw, introducing the risk of cross-contamination of potentially harmful pathogens that will not be destroyed in the cooking process before consumption."

Cross-Contamination

Cross-contamination can occur with biological risks, such as pathogenic bacteria or viruses, or with chemical risks, such as chemical contaminants or allergens. It is a particular challenge in the case of meal kits since multiple food products, which may be sourced from multiple suppliers, may be processed in the same facility and are then packed into the same box. Meal kits often contain ingredients in the same box that are to be cooked and eaten raw, introducing the risk of cross-contamination of potentially harmful pathogens that will not be destroyed in the cooking process before consumption.

Cross-contamination can occur at other stages of a meal kit, as well. Once all the ingredients are inside the meal kit, proper packaging is necessary to ensure that ingredients are kept separate, especially high-risk foods such as raw meat, poultry, eggs, seafood, and dairy. This packaging must be able to retain its integrity throughout the transport process, which may include rough handling. Finally, customers should be provided with education on how to unpack their meal kits to reduce cross-contamination, as well as on safe food handling techniques to use and practices to reduce cross-contamination include:

- *Ingredient sourcing*
  - Verifying the food safety protocols from all ingredient suppliers
- *Food processing*
  - Keeping raw meats separate from ready-to-eat foods (e.g., separate chopping board, utensils, equipment, and storage areas)
  - Implementing stringent worker hygiene protocols (e.g., handwashing)
  - Implementing cleaning and sanitizing protocols for food contact surfaces
- *Packaging*
  - Ensuring that outer packaging can withstand transport and handling, and protects the ingredients from damage
  - Developing cleaning and sanitization protocols for outer packaging if it is reusable (i.e., returned by customer)

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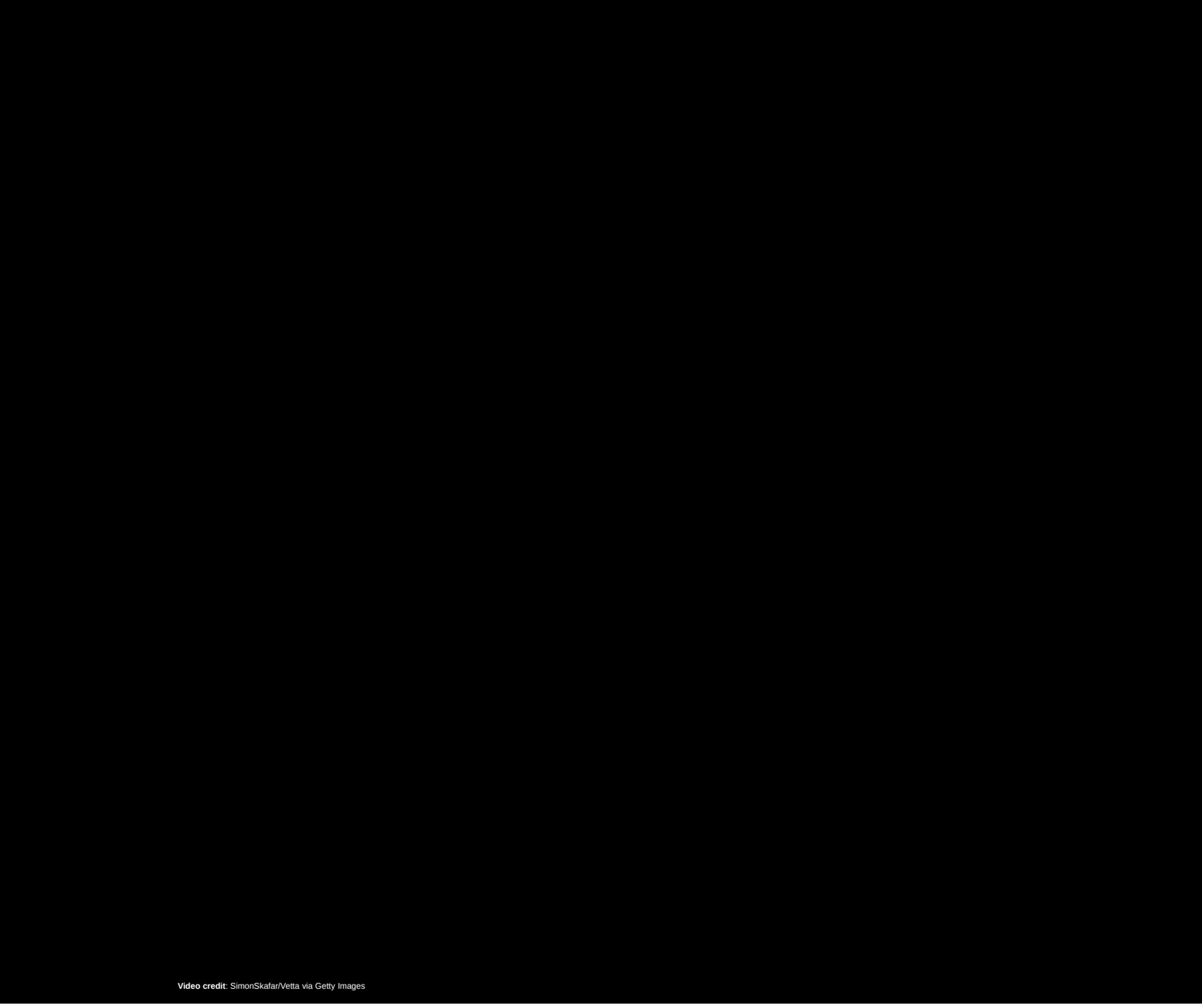

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Pre-Harvest Strategies to Reduce Foodborne Pathogens in Red Meat Production

Many new pathogen reduction interventions have been implemented in recent years on the post-harvest side of animal-derived food production

By Todd R. Callaway, Ph.D., Associate Professor; Alexander Stelzleni, Ph.D., Professor and Graduate Coordinator; and Jeferson M. Lourenco, Ph.D., Assistant Professor, Department of Animal and Dairy Science, University of Georgia

Consumers expect and rightfully demand a plentiful supply of affordable, safe, and wholesome red meat. Concerns about the safety of meat have been important to the industry, the public, and the government since the implementation of the Pure Food and Drug Act of 1906. Unfortunately, despite the effort expended in controlling foodborne illnesses in the U.S., foodborne pathogens cost the GDP more than $17.6 billion each year in direct and indirect costs.[1]

One of the most notable improvements to food safety is the implementation of Hazard Analysis and Critical Control Points (HACCP), which has been globally adopted as a method to systematically improve food safety. The implementation of other procedures, such as "test and hold" for ground beef prior to shipment to consumers, has significantly improved consumer safety. As a result of these systematic improvements in the food supply chain driven by industry and government actions, the U.S. food supply is safer than ever before.

While the number of foodborne bacterial illness cases and outbreaks impacting consumers has been reduced, too many foodborne illnesses still occur. Most foodborne pathogenic bacterial reduction processes have focused on reducing pathogen loads in processing plants. Processing plants do an excellent job of reducing pathogen levels on carcasses during the processing and retail phases of animal-derived food production, and many new interventions have been implemented in recent years on the post-harvest side of the continuum.

Fecal foodborne pathogen shedding by the live animal is correlated with levels of carcass contamination; therefore, if the pathogen burden entering the processing facility in and on food animals can be reduced, then pathogen reduction strategies in the plant can be more effective in controlling the pathogen load in finished products. Furthermore, foodborne pathogenic bacteria are not only transmitted to humans through animal-derived foods and can reach humans via drinking water, or on irrigated vegetables, and can be transmitted via dust or other vehicles. Recent years have also witnessed an increasing frequency of illnesses in schoolchildren who have visited petting zoos or open farms. Thus, developing strategies to reduce foodborne pathogens in live animals can have impacts in more than just the food chain.

Foodborne pathogenic bacteria [e.g., *Salmonella*, *Campylobacter*, *Listeria*, and Shiga toxin-producing *Escherichia coli* (STEC) O157:H7 and associated serotypes] are commonly found in the gut of food animals, as well as in on-farm production environments (e.g., manure, water, migratory birds, rodents). Many of these foodborne pathogenic bacteria do not cause detectable illnesses in food animals, and so are nearly invisible members of the gut microbial populations found in the on-farm production environment where animals are produced. For example, STEC is a cluster of pathogenic bacteria that cause bloody diarrhea in humans. These bacteria do not cause any illnesses in cattle, but they can cause profound kidney damage in humans, especially in children under seven years of age. While STEC-related illnesses have been often associated with consumption of undercooked ground beef or via contaminated produce, pathogen transmission to humans can occur through contaminated drinking or recreational water, contact with cattle, pen surface contamination, and through human-to-human contact. Due to the profound impacts on both children and adults, seven STEC strains were declared as adulterants in ground beef (but not in intact beef products). As a consequence of this declaration, the U.S. beef industry invested heavily in research on food safety improvements, which has resulted in a significant decrease in the number of human STEC illnesses.

Most foodborne pathogenic bacteria behave similarly to "typical" bacteria in the gut of food animals, which has led researchers to mine ecological concepts to develop strategies to reduce pathogen entry to the food chain at the processing plant and beyond. The logic behind investing resources in developing pre-harvest intervention strategies is demonstrated through the following:

1. Reducing the amount of pathogens entering processing plants will reduce the pathogen burden entering such plants, rendering in-plant interventions more effective
2. Reducing horizontal pathogen spread from infected animals during transport and lairage
3. Reducing the pathogen burden in the environment (e.g., dust and pen surfaces) and wastewaters that potentially contaminate crops (e.g., leafy greens)
4. Reducing the risk to those in direct contact with animals (e.g., petting zoos and open farms).

To control pathogens in the live animal, several potential reduction strategies have been developed for use on-farm in live animals. These approaches can be grouped loosely into broad categories:

1. Animal management and transport practices
2. Feed and water management
3. Live animal treatments.

While some of these pathogen reduction strategies are available today, many remain to be developed in the near future and are promising to help secure the safety and integrity of the food supply from farm to fork.

"Seasonality may require specific interventions to be utilized more during peak shedding season, however, at present, the seasonal use of interventions is not recommended."

Animal Management and Transport Practices

Good animal management is critical to the production of healthy and efficient food animals, and is often referred to as "Good Agricultural Practices" (GAP). No typical management procedures directly affect colonization or shedding of any foodborne pathogens; yet, impacts from bad animal care and management (e.g., stress, animal health, and water run-off) can impact pathogen shedding and recirculation/colonization of pathogens within a pen or herd. Good animal management techniques, production hygiene, stress-reducing handling practices, and overall good animal husbandry play an important role in food animal production and should be followed. For example, STEC and *Salmonella* excretion in cattle is highest in the late spring through late summer; this seasonality is reflected in the "summer peak" of illnesses in humans. Seasonality may require specific

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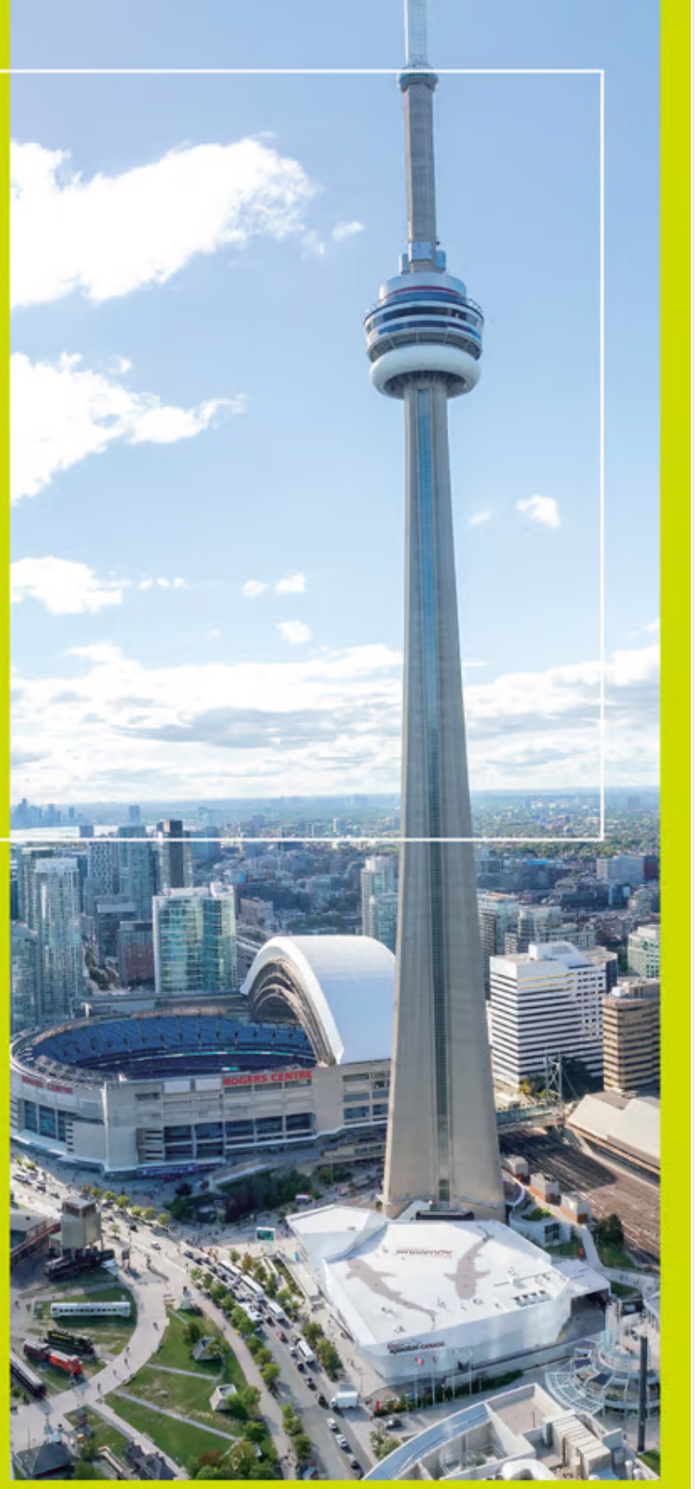

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SCROLL DOWN

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Food Documents as Food Fraud Facilitators

Food fraud is accomplished in numerous ways, and document fraud may be one of the easiest ways for food fraudsters to operate undetected

Fraud, which is deception used for economic or personal gain, has been around since the beginning of human history. Although the technologies used to commit fraud have evolved over time to adapt to structural changes in society (e.g., fraud in person vs. fraud online), many fraudulent schemes have withstood the test of time. Human social behavior, the way we think, how we connect and relate to others, and how we are taught to trust people we do not know well are products of human nature and have remained persistent and predictable throughout the years. This predictability makes us, and the organizations we work for, susceptible to fraud.

However, fraud schemes are rarely successful without a person or thing making the fraudsters' actions unnoticeable or credible. Documents are one such category of thing that has made fraud easier to commit and more difficult to detect. Documents are pervasive throughout society, and we have been programmed to generally trust the authenticity of the documents presented to us. For example, when presented with an identification credential such as a driver's license or passport, the receiver rarely questions the document's validity. After all, the person presenting the identity document went through an identity verification process. Another example is when a certificate of analysis (COA) is presented to the customer by the supplier to demonstrate that the shipment received meets the agreed-upon specifications, the customer rarely questions the authenticity of the COA. The supplier has presumably been vetted, is likable, and appears trustworthy.

While reading this, you might be thinking, "Not me. I am intelligent, skeptical, and I'm confident I would be able to spot a fake document if one were presented to me." Are you sure? How would you determine the authenticity of the document presented to you? If you are receiving hundreds of documents each day, then how long would it take you to complete the authentication process for each document? Practically speaking, most people do not have time to investigate and verify the documents they encounter in their daily routines. Moreover, life would become an inefficient and unbearable experience if every person and organization were trying to independently verify most of the documents they received daily. So, for businesses and society to operate efficiently, we must grant a level of trust to the people and documents we encounter in both our personal and professional lives. Of course, fraudsters understand this reality very well and use it to their advantage. In this regard, documents are used to facilitate their illicit activities.

The food industry relies on a countless number of documents to keep food supply chains moving quickly and efficiently, to help ensure food safety, to satisfy legal and regulatory requirements, and to communicate product information to consumers. However, the food industry's reliance on these documents also provides opportunities for fraudsters to exploit food fraud countermeasures and to perpetuate food fraud events. This article explains what those documents are, how they facilitate food fraud, and why incorporating a review of food documents as part of your food fraud vulnerability assessment can go a long way in reducing the fraud opportunity.

Food Fraud Prevention is Challenging

Food fraud has been a part of human societies since antiquity. However, until recently, it was not a focal point for the food industry or regulators as the focus has traditionally been on the unintentional contamination of food products. As a result, food fraudsters did not need to expend a great deal of effort to carry out a food fraud event, and the risks of getting caught were negligible. Now that food companies are well aware of the food fraud risks, they are actively assessing their food fraud vulnerabilities and employing food fraud prevention countermeasures when deemed necessary.

Indeed, we have come a long way in understanding the risks associated with food fraud to the food industry and consumers. Food fraud is an intentional act where an individual or business deceives others using food, food products, or food packaging for economic gain. Food fraud takes a variety of forms, but the most common techniques used by food fraudsters are substitution, adulteration, counterfeiting, and mislabeling. Given that food fraud has become a focal point for the food industry and government regulators such as the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the European Food Safety Authority (EFSA), and the China Food and Drug Administration (CFDA), the effort food fraudsters are required to expend to carry out a food fraud event has greatly increased. As a result, food fraudsters are innovating. They do this by making decisions based on their ability to imagine new ways to evade current security measures, execute them at speed, and avoid detection to keep the fraud going as long as possible. If they did not innovate, then we would not need to be constantly assessing our food fraud risks and vulnerabilities. In effect, we would have already won, and food fraud would have gone the way of rinderpest cattle disease.

Since food fraudsters have the first-move advantage and can rapidly innovate, the food industry has often found itself operating reactively (e.g., the European horsemeat in beef scandal). Therefore, prevention is the goal. We do not want to catch food fraud; we want to prevent it before it happens. However, food fraud prevention can be challenging because it requires businesses to imagine which food or food product the fraudsters will attack, how they will attack it, how they will evade current security measures, and how they will respond to future countermeasures.

> **"Structural changes in routine activity patterns of food producers, suppliers, workers, and consumers can impact food fraud by increasing or decreasing the opportunity for fraud."**

Food Fraud Prevention and Fraud Facilitators

Food fraud prevention is based on a group of crime theories that focus on crime events. In this regard, the place of crime matters and the role that immediate environmental circumstances play in making food fraud more or less likely to occur is important. Three theoretical perspectives that have been developed to understand crime events and explain food fraud are: Routine Activity Theory, Rational Choice, and Situational Crime Prevention. When combined, these perspectives capture the thought process of fraudsters: how they make the decision of when and where to commit food fraud, how they perceive a target to be suitable, and how guardians can prevent food fraud. Some readers may be familiar with Routine Activity Theory and Situational Crime Prevention, but they may not have been exposed to the concept of fraud facilitators and their role in food fraud. Before introducing the concept of fraud facilitators, a brief review of the three theories identified above will be helpful.

While exploring the relationship between humans and their environment, Cohen and Felson[1] argued that crime can be understood by recognizing individuals' routine activity patterns. According to the Routine Activity Theory, three factors must be present for a crime to occur: a motivated offender, a suitable target, and the absence of a capable guardian. Of these three factors, guardianship may be the most important component in preventing a crime event. By disrupting the interaction between a motivated offender and a suitable target, a guardian can directly or indirectly prevent fraud from occurring.

To better visualize and understand this interaction, John Eck[2] proposed that the "crime triangle" should consist of two layers (Figure 1). The inner layer represents the three elements necessary for a crime to occur, and the outer layer represents the three types of guardians that may prevent a crime. According to Eck, the intervention of any one guardian can be sufficient to prevent a crime from taking place. Felson and Boba[3] explained how the three forms of guardianship are interconnected in the sense that a crime is accomplished when a motivated offender moves away from handlers, toward a place without a manager, and toward a target without a guardian. When thinking about the food industry, the probability of these three elements converging in space and time is influenced by routine activity patterns of food producers, suppliers, workers, and consumers moving along the food supply chain. Structural changes in these patterns can impact food fraud by increasing or decreasing the opportunity for fraud.

FIGURE 1. The Crime Triangle (Adapted from Clarke and Eck[4])

While the Routine Activity Theory identifies the necessary elements for food fraud to occur, the Rational Choice perspective describes how fraudsters make decisions. The Rational Choice perspective asserts that food fraud results from calculated, reasoned choices using a cost-benefit analysis. Food fraud is more likely to occur when the expected gain exceeds the expected costs. Consequently, the decision to commit food fraud is a two-part process. First, individuals must be willing to commit the fraud, and then they must decide what type of food fraud they want to commit (e.g., counterfeiting, substitution, adulteration). These decisions are greatly influenced by the fraudsters' assessment of the immediate situation.

Situational Crime Prevention is the applied side of routine activity theory. The goal is to reduce fraud opportunities through the manipulation of the immediate environment to deal with specific forms of food fraud. Therefore, manipulating situational factors and altering the perceived benefits and costs of food fraud could change an offender's decision-making process. Unlike many generic approaches to crime prevention, which apply various techniques to a broad range of problems, Situational Crime Prevention focuses on a precise problem, in a specific place, under particular circumstances to make the target unattractive to criminals. Fraudsters make choices based on their assessment of potential opportunities. Therefore, understanding how fraudsters see events is important to preventing food fraud because almost all food fraud prevention strategies will involve changing the food fraudsters' perceptions of fraud opportunities.

Fraud facilitators help fraudsters commit and perpetuate food fraud. Three types of fraud facilitators are defined: physical, social, and chemical. Each type of facilitator helps fraudsters get around food fraud countermeasures. Physical facilitators (e.g., computers, documents, melamine used to mimic protein in milk) help fraudsters overcome prevention measures that increase risk or effort. Social facilitators encourage fraud by enhancing the rewards from the food fraud event, legitimating excuses to commit food fraud, or encouraging participation in food fraud, which often occurs with members of criminal networks. Chemical facilitators include substances like drugs and alcohol, which increase the fraudsters' ability to ignore risks or miscalculate the costs and benefits of their fraud scheme.

Documents as Food Fraud Facilitators

Documents are one of the primary food fraud facilitators and can be defined as any material that carries an explicit or implied message.[5] Although documents are often associated with paper containing handwriting or computer-generated text, in its most broad interpretation, writing or printing on a wide range of substrates other than paper can also be considered documents. For example, graffiti left on the side of a building or a baseball containing the signature of a baseball player are both considered to be documents.

Document fraud is the use of an altered, counterfeit, or forged document, by an individual or group, for financial, political, or social purposes.[6] Although the myriad of documents used in the food industry can be classified under the general document definition provided above, for food fraud prevention purposes, food documents will be defined as pieces of written, printed, or electronic matter that are used to provide evidence or information about food products, food ingredients, or food packaging. Some examples include documents related to imports and exports, bills of lading, certificates of analysis, credence attribute statements, invoices, sales receipts, as well as shipping, packaging, and product labels. Since documents are used to facilitate food fraud events,[7] food document fraud can be specifically described as acts of deliberate counterfeiting, faking, altering, or forging of a food document to facilitate food crime.

Every industry is susceptible to document fraud, and the food industry is no exception. However, food document fraud can have more devastating consequences than document fraud in other industries due to its potential negative impact on public health.[8] Moreover, the number and type of documents being used throughout the food supply chain, the speed at which they move, and the ease with which they are accepted as genuine, provide food fraudsters with numerous fraud opportunities with little risk of detection. In fact, most food fraud events are facilitated and perpetuated by fraudulent documents. As a result, it is important to understand the risks associated with the use of documents in the food supply chain so that countermeasures can be employed to reduce food document fraud, making it more difficult for food fraudsters to commit fraud.

Traditionally, food document fraud has not been systematically considered when food companies perform their annual Food Fraud Vulnerability Assessments (FFVA). Since research on food document fraud is relatively nonexistent, as an initial step to understanding the risks associated with the use of documents in the food supply chain, an ongoing survey is being conducted by researchers with the Food Fraud Prevention Academy (formally Michigan State University's Food Fraud Initiative). The Food Document Fraud Survey (FDFS) is being distributed among food industry professionals and expert groups to investigate their perception of food document fraud and to identify the documents that are most commonly used, altered, counterfeited, and forged in the food industry.

Results obtained from the FDFS indicate that documents are a latent vulnerability in the food supply system and most organizations are not prepared to identify and evaluate questioned documents. The study participants identified 35 different documents that they deal with on a regular basis. Of these, the five most reported were: COAs (56 percent), credence attribute statements or certifications (46 percent), bills of lading (22 percent), laboratory analysis test results (22 percent), and import and export documents (16 percent).

When asked about their experience with food document fraud, 86 percent of the participants reported being concerned about fraudulent documents entering the food supply chain in general and their organization, more specifically. While almost half of the study participants had encountered an altered or fake document (44 percent), the majority were unsure if they had encountered an altered or fake document (56 percent). This is an important finding because it shows that fraudulent documents are being encountered by food industry professionals, and it reveals the difficulty people experience in identifying questioned documents.

The fact is that the inability of food industry workers to identify and intercept fraudulent documents provides an opportunity that is being exploited by food fraudsters. When asked about their organization's capacity to identify and evaluate questioned documents, only 35 percent of the study participants reported having a process in place to identify questioned documents, and 28 percent reported having a document examiner or consultant on retainer. In other words, more than two-thirds of the study participants admitted that their organization did not have a process in place to identify questioned documents. Considering this, 90 percent of participants were interested in learning more about document fraud, and 72 percent were interested in starting a document fraud prevention program.

Takeaway

Food fraud is accomplished in numerous ways, and document fraud may be one of the easiest ways for food fraudsters to operate undetected. Considering the importance documents play in the food supply chain and the ease with which they can be altered, counterfeited, or forged, it is imperative that food organizations add a document fraud review to their prevention strategy project list. The sheer number and types of documents encountered by food industry workers on a daily basis can be overwhelming. Considering all of the different types of food documents that could be fraudulent, this adds up to a considerable amount of risk.

A good first step in document fraud prevention and response is understanding the types of documents commonly used within your organization and identifying those targeted by fraudsters. Begin by creating broad document categories for financial records, transportation records, and certification records. Next, identify and place each type of document used within your organization into one of these broad categories. Finally, review the different document types and rank them based on their level of risk for fraud.

This initial document screening process will offer some insight as to where your biggest document fraud risks are and where the document fraud is most likely occurring. Consider how the information obtained from your food document fraud analysis fits into and informs your food fraud vulnerability assessment. The important thing is to get started. Once you have a food document fraud assessment process in place, you can continue to refine it. Document your current state and needs, and create some food document fraud next steps. ■

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Recent Outbreaks of Listeriosis Linked to Fresh, Soft Queso Fresco-Type Cheeses in the U.S.

Since 2000, more outbreaks have been attributed to cheeses made from pasteurized milk, which have been contaminated by L. monocytogenes *during the cheesemaking process*

In 2020,the EU and the U.S. were the world's leading cheese producers, accounting for roughly 70 percent of global production. Overall, global cheese production is projected to continue increasing at least until 2027, as developed nations are expected to increase their milk production by roughly 9 percent.[1]

Concurrently, cheese consumption has increased around the world, with the U.S. and the EU being the main cheese-consuming areas.[1] Generally, cheeses can be categorized as soft, semi-soft, soft ripened, or hard, depending on their moisture content and how they are made. These parameters affect their sensory attributes, as well as their ability to support growth of *Listeria monocytogenes*. Fresh, soft, un-ripened cheeses have not been aged and have high moisture in the range of 40–80 percent, which limits their shelf life.

Queso fresco-type cheeses (QFTCs) include fresh, soft cheeses that have not been extensively aged; these have been classified as "fresh, soft cheeses" in risk assessments conducted jointly by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).[2] These types of soft cheeses are typically white or off-white in color, have high moisture, lower salt content, low acidity, and a shorter shelf life than aged cheeses, and require refrigeration for safety. In the U.S., cheeses must be made from pasteurized milk or cream, with the exception of some cheeses that are aged for 60 days or more. Depending on their country of origin, some of the more popular fresh, soft QFTCs may have different names for the same type of cheese or the same names for different types of cheese, such as Oaxaca, Asadero, Queso Blanco, Queso Fresco, Ranchero, and Panela. In 2009, U.S. producers manufactured approximately 206 million pounds of QFTC, and by 2019, that number climbed to roughly 333 million pounds, with the U.S. per-capita consumption doubling during the same timeframe.[3]

QFTCs and *Listeria*

An estimated 1,600 cases of foodborne listeriosis occur annually in the U.S.[4] The illness is caused by the consumption of foods contaminated with *L. monocytogenes* and primarily affects those with weakened immune systems, people over the age of 65, and pregnant people. Infection can result in serious outcomes such as septicemia, meningoencephalitis, pregnancy loss, and/or death.

Historically, outbreaks of listeriosis linked to fresh, soft QFTC consumption have been linked to cheeses made from unpasteurized milk. Since 2000, more outbreaks have been attributed to cheeses made from pasteurized milk, which have been contaminated by *L. monocytogenes* during the cheesemaking process.[5] Proper pasteurization eliminates *L. monocytogenes*, but cheesemaking involves several steps where the ready-to-eat (RTE) product is exposed to the environment after pasteurization of milk or cream, allowing for potential contamination by *L. monocytogenes* from the manufacturing environment. Fresh, soft QFTC can support the growth of *L. monocytogenes* because of their relatively high pH, high moisture content, and low salt levels. Additionally, QFTCs are typically handcrafted by smaller producers where the manual nature of production, which is more common in smaller facilities, can exacerbate this risk. It is crucial that manufacturers identify and control hazards associated with making these products.

Using data from the Foodborne Disease Outbreak Surveillance System, the U.S. Centers for Disease Control and Prevention (CDC) found that 58 outbreaks of listeriosis were reported in the U.S. from 1998 to 2014; of these, 17 (30 percent) of the outbreaks were associated with soft cheeses, resulting in 180 illnesses, 14 fetal losses, and 17 deaths.[5] Eleven of the 17 cheese-associated outbreaks were due to consumption of QFTC, and the 11 outbreaks accounted for 98 (54 percent) of the cases of listeriosis.[5] In comparison, the remaining six of the 17 outbreaks were linked to consumption of sheep's milk cheeses, Eastern European-style cheeses, Middle Eastern-style cheese, Italian-style cheese, blue-veined cheese, and soft-ripened cheeses.[6] Outbreaks of listeriosis due to fresh, soft QFTC often disproportionately affect Hispanic people who are pregnant and their newborns, and can result in pregnancy loss, stillbirth, or death of the newborn.[6,7,8] Additionally, people who are 65 years and older and people with weakened immune systems are at higher risk.[9] An often underreported aspect of listeriosis outbreaks includes the estimated health care costs. The authors estimate the most recent listeriosis outbreak linked to fresh, soft QFTC in February 2021 to cost approximately $45.96 million in lost consumer health, accounting for underreporting/diagnosis.[10,11]

FDA works closely with CDC, state, and local partners to coordinate listeriosis investigations in response to multistate outbreaks. Here, the authors present key findings of outbreak investigations from 2014–2021 that have been linked to the consumption of fresh, soft QFTC where a firm of interest was identified in the U.S. They also outline some of the specific circumstances that all cheeses may encounter, particularly smaller manufacturers of fresh, soft QFTC. The authors' goal is to provide lessons from these outbreaks and

"Fresh, soft QFTC are also sold at deli counters where they may be cut and repackaged, which presents cross-contamination concerns that may skew epidemiologic and traceback data."

Outbreak Investigations of Listeriosis Linked to QFTCs

Throughout the years, fresh, soft QFTC outbreaks have faced several challenges, including a small number of ill people. Interviews are often completed with a surrogate (someone speaking on behalf of or translating for the ill person), and language barriers, which might require use of a translator, present challenges in obtaining accurate exposure information. *L. monocytogenes* has a long incubation period (varying from a few days to 90 days) and, as a result, food exposure recollection may be very difficult for ill people when trying to determine the food that made them sick.[12] When exposure information is available, exposures to multiple types of fresh, soft QFTC and/or multiple QFTC brands in the timeframe before illness are often reported.

Fresh, soft QFTC are also sold at deli counters where they may be cut and repackaged, which presents cross-contamination concerns that may skew epidemiologic and traceback data. Additionally, the same fresh, soft QFTC brand may be made by multiple QFTC manufacturers. These limitations significantly impact investigators' ability to identify the source of the outbreak and, as a result, several outbreaks that were suspected to be linked to fresh, soft QFTC remain unsolved.Since 2014, four investigations have been conducted for listeriosis outbreaks linked to the consumption of fresh, soft QFTC made with pasteurized milk (Table 1). Three of the four investigations resulted in the implicated cheeses being recalled from the market to protect public health. All three firms ceased manufacturing cheeses, while the fourth investigation did not confirm a specific brand or firm associated with the outbreak.

TABLE 1. A Summary of Outbreak Investigations of *Listeria monocytogenes* Infections Linked to QFTCs, 2014–2021[13–17]

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In 2014, two outbreaks of listeriosis were linked to QFTC. The first outbreak investigation, which began early that year, included a total of eight illnesses reported in two states; seven ill people were hospitalized.[14] Five illnesses were related to pregnancy (two mother-newborn pairs, and one in a separate newborn),[14] and three ill people were adults (non-pregnancy related). One person died. All eight ill people reported Hispanic ethnicity. Exposure information was available for five ill people; two were mothers interviewed for the mother-infant pairs.

The five adults reported consuming QFTC from the same grocery chain, and three specifically reported consuming cheese made by the firm of interest. Testing of multiple cheese products collected from the grocery chain was performed by state partners at the Maryland Department of Health and Mental Hygiene and Virginia's Division of Consolidated Laboratory Services (VA DCLS). Pulsed-field gel electrophoresis (PFGE) of the *L. monocytogenes* isolates from the firm's cheese products (a single strain) were a match to the isolates from ill people in the outbreak, adding further evidence that the firm's cheese products were the source of the outbreak. As a result, the firm voluntarily recalled all potentially contaminated cheeses. Whole genome sequencing (WGS), completed after the recall, confirmed the genetic relationship between the cheese isolates and the clinical isolates from ill people. An investigation at the firm's facility found insanitary conditions and recovered *L. monocytogenes* isolates from environmental sampling, including the cheese processing room and various pieces of equipment.

Specifically, investigators found the following insanity conditions:

1. The roof was leaking so profusely that water was dripping into the cheese processing room, including onto the cheese processing equipment and storage tanks
2. Standing water was present on the floor throughout the cheese curd processing room in proximity to the cheese vats and in the storage rooms
3. Metal roof/ceiling and metal supports exhibited a rusted appearance with metal flaking, precluding effective cleaning and sanitizing
4. Food residues were found on equipment after cleaning had been performed
5. Openings to milk storage tanks and transfer piping were not capped to prevent contaminants from entering or contaminating food contact surfaces
6. Floors, walls, and equipment were deteriorated and in disrepair, including processing equipment and storage vats with rust holes and floors with rough concrete deterioration.

To immediately ensure that contaminated products would not be distributed, FDA suspended the firm's food facility registration as its QFTC products presented a reasonable probability of serious adverse health consequences or death to humans. Furthermore, a Decree of Permanent Injunction was filed to ensure that longstanding corrective actions would be implemented if the firm resumed operations.[14]

The second outbreak investigation took place in late 2014 and included nine ill people from six states, with eight of the nine hospitalized.[13] Among the nine illnesses, six illnesses were related to pregnancy, with two fetal losses reported and two illnesses in newborns. One death was reported in an infant.[13,17] All nine ill people reported Hispanic ethnicity, and eight of the nine ill people reported consuming QFTC. Food exposures for the pregnant person were collected for infants for the four weeks prior to illness onset. Cheese exposure for one patient was unknown. In July 2014, VA DCLS identified *L. monocytogenes* in Quesito Casero cheese, which was collected during routine sampling from a retail location. As a result, in August 2014, FDA inspected the firm's processing facility and found failures to comply with Current Good Manufacturing Practice (CGMP) requirements.[18]

Additionally, FDA collected environmental samples during the inspection, recovering isolates of *L. monocytogenes* that were highly related by WGS to isolates from the VA DCLS retail sample of Quesito Casero cheese and all isolates from ill people. This WGS data indicated a high likelihood that these isolates had originated from the same source. The manufacturer voluntarily recalled Quesito Casero cheese and during that month, it expanded the recall on multiple occasions. Another FDA inspection was conducted at the facility in October 2014 in response to a cluster of four listeriosis illnesses (part of the total nine illnesses of the outbreak). The clinical isolates in these four illnesses were closely matched by WGS to the isolates recovered from the Quesito Casero retail cheese sample collected by VA DCLS and the FDA environmental isolates collected in August 2014. At the end of the inspection, the owner informed FDA that the firm would shut down operations and discontinue processing and repackaging of cheese products.[18]

The inspection closed on December 16, 2014 and revealed that the firm failed to clean and sanitize equipment in a manner that protects against contamination of food, food contact surfaces, or food packaging materials. Additionally, the firm failed to report a reportable food to the Reportable Food Registry[19] within 24 hours of determining that there is a reasonable probability that the use of, or exposure to, the reportable article of food will cause serious adverse health consequences or death to humans or animals.[18] Based on violations identified during these inspections, FDA issued a Warning Letter to the manufacturer on July 8, 2015.[18] The manufacturer responded to the Warning Letter on July 20, 2015, indicating that dairy products were not being processed at that time and had not been processed since receiving the letter. On November 15, 2016, the U.S. Department of Justice announced that the owner of the firm was sentenced to 15 months in prison for distributing cheese contaminated with *L. monocytogenes*.[20]

In late 2019, an outbreak of listeriosis occurred with fresh, soft QFTC identified as a suspect source. Despite the epidemiologic information and inspection issues identified, available epidemiologic and laboratory data did not definitively link the ill people to the fresh, soft QFTC manufacturer. As a result, fresh, soft QFTC was not confirmed as the source of this outbreak.

A total of four ill people from three states were reported. Three ill people were hospitalized. Three illnesses were related to pregnancy, with one resulting in fetal loss. No deaths among the ill people were reported. All four ill people reported Hispanic ethnicity. Two ill people reported consuming the same brand of fresh, soft QFTC, with one specifically reporting Queso Fresco. In January 2020, FDA conducted an inspection at the QFTC manufacturer[15] and subsequently issued a Warning Letter. Environmental and product samples collected during the inspection did not identify *L. monocytogenes*; however, *L. grayi* and *L. innocua* were found in the environment. ... survive in the same environment.

"Listeriosis outbreaks associated with fresh, soft QFTCs continue to present a significant food safety challenge. These outbreaks underscore the importance of compliance with food safety regulations by fresh, soft QFTC manufacturers."

According to the warning letter,[15] the firm:

1. Did not conduct a hazard analysis for each type of food manufactured, processed, packed, or held at its facility to identify and evaluate known or reasonably foreseeable hazards to determine whether there were any hazards requiring a preventive control
2. Did not establish and implement preventive controls to provide assurances that any hazards requiring a preventive control would be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility would not be adulterated
3. Did not prepare/have prepared and did not implement a written food safety plan for any of the products manufactured in its facility.

The most recent outbreak of listeriosis linked to the consumption of fresh, soft QFTC occurred in 2021.[16] A total of 13 ill people were reported from four states. Twelve of the 13 ill people were hospitalized. Four illnesses were related to pregnancy, and two resulted in fetal loss. One death was reported among the ill people. Twelve of the 13 ill people reported Hispanic ethnicity. Eight people reported consuming QFTC; among those, seven reported consuming queso fresco. Four people reported the same QFTC brand reported by ill people in the 2019 outbreak discussed above. The Connecticut Department of Public Health collected two samples of the reported brand Queso Fresco cheese and recovered isolates of *L. monocytogenes* related to the outbreak strain by WGS. In February 2021, FDA initiated an inspection at the fresh, soft QFTC manufacturer. As a result, the QFTC manufacturer ceased production and repackaging at its facility and conducted a voluntary recall. This recall was later expanded to include all cheeses handled at the firm.

General Facility Investigation Observations

These FDA inspections of fresh, soft QFTC firms linked to listeriosis outbreaks showed deviations from regulatory requirements set forth in 21 CFR Part 110 (in the outbreaks in 2017 and before), or 21 CFR Part 117 (in the outbreaks 2019 and after), as noted in the Inspectional Observations FDA Form 483,[21] a notification to the firm's management of objectionable conditions observed by investigators. All fresh, soft QFTC firms linked to the outbreaks described in this article had fewer than 500 employees—the definition of a small facility, as outlined in 21 CFR Part 117. Most of these facilities were not kept in good repair. Examples included water leaking from the roof, floors in disrepair, and issues with condensate or pooling water. *L. monocytogenes* or *Listeria* spp. were detected in the environment during the inspections of some of the firms, and *L. monocytogenes* was isolated from the product in two of the outbreaks.

Common observations in small fresh, soft QFTC manufacturing facilities associated with listeriosis outbreaks include:

- Inadequate cleaning and sanitizing of facilities resulting in issues such as standing water and cross-contaminated food contact surfaces
- Inadequate pest control
- Poor employee hygiene practices, including improper use of gloves
- Inadequate cleaning, sanitizing, and maintenance of equipment and/or utensils
- Inadequate separation between pasteurized and unpasteurized dairy products
- Failure to manufacture, package, and store products under conditions necessary to minimize the potential for microbial growth and contamination
- Inadequate hazard analysis, lack of food safety plan, and failure to conduct environmental testing for *Listeria* spp. were also noted for one of the fresh, soft QFTC firms.

Certain Requirements Applicable to Cheese Manufacturers

FDA has established in 21 CFR Part 117 a regulation titled, "Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food" (Part 117). Part 117 establishes requirements for CGMPs for human food, for hazard analysis and risk-based preventive controls for human food (PCHF), and related requirements.[22] Manufacturers of cheeses, including fresh, soft QFTC, are required to comply with CGMP requirements and, unless specific exemptions apply, PCHF requirements (e.g., very small businesses are "qualified facilities" subject to modified requirements). The CGMP requirements address areas such as employee hygiene, equipment maintenance, training, adequacy of water supply, sanitary design and operation, and process controls, all of which are important in preventing the contamination of food. The PCHF requirements include steps that manufacturers must take to identify and significantly minimize or prevent food safety hazards.

Cheese manufacturers subject to the PCHF requirements must implement a written food safety plan (FSP).[23,24] Within the FSP, these manufacturers must conduct a hazard analysis and determine if any identified hazards require a preventive control. For RTE food, such as fresh, soft QFTC, the hazard analysis must evaluate the hazard of contamination with environmental pathogens (e.g., *L. monocytogenes*) whenever the RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.[24] When manufacturers determine within the hazard analysis that one or more preventive controls are required, they must establish the preventive control(s) with the required preventive control management components (e.g., monitoring, corrective actions, and verification), as appropriate to the nature of the preventive control and its role in the food safety system.

Examples of preventive controls that could be implemented to control *L. monocytogenes* in cheese production are outlined in Table 2. The PCHF requirements include environmental monitoring and finished product testing as ...

TABLE 2. Some Provisions of CGMP, Hazard Analysis, and Risk-Based PCHF Regulation Applicable for Control of *Listeria monocytogenes* in Facilities Subject to 21 CFR Part 117 and Making Soft, Fresh Cheese[24]

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Food Safety and FSMA Resources for QFTC Manufacturers

FDA has developed guidance documents that are available on FDA's website to help cheese manufacturers be better prepared for compliance with the Food Safety Modernization Act (FSMA) and applicable federal rules and regulations.[25] Cheese manufacturers will find *Draft Guidance for Industry: Control of* Listeria monocytogenes *in Ready-To-Eat Foods* and *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* to be valuable resources.[22,26] These guidance documents, when finalized, will represent FDA's current thinking. They include information about the pathogen, environmental monitoring, and product testing. The FSMA Technical Assistance Network (TAN) is a central source of information for questions related to FSMA rules, programs, and implementation strategies.[27] Anyone can submit questions for review and response by subject matter experts.

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public-private alliance comprising industry, academic stakeholders, and government representatives, with the goal of developing educational material, training, and outreach programs to support compliance with the prevention-oriented standards of FSMA.[28] FSPCA organizes training courses and also develops and shares a plethora of other resources and helpful information. FSPCA Participant Training Courses are held regularly and can provide helpful information to small-scale cheese manufacturers. Additionally, FDA's Food Safety Plan Builder is a tool designed to assist owners and/or operators of food facilities with the development of FSPs that are specific to their facilities and meet the PCHF requirements.[23]

Many additional resources are available to fresh, soft QFTC manufacturers. These resources include university food safety extension specialists who can help cheese manufacturers, particularly smaller ones, develop an FSP for their facilities, conduct the hazard analyses, and perform risk assessments of their processes, helping ensure that they are producing the safest product possible. Regulatory partners and food safety experts at state and local government agencies generally inspect milk processing plants and collect samples of milk and milk products to ensure consumer safety. More importantly for small-scale manufacturers, state and local government agencies can share important guidelines, licensing, and compliance information. Cheese manufacturer associations and other trade organizations are groups designed to deliver the latest in food safety news to dairy product manufacturers, processors, and their suppliers. These associations can share guidance materials intended to facilitate the development of food safety risk mitigation steps by manufacturers. Additional resources offered through dairy extension programs, other organizations, and digital resources such as online training, blogs, social media, and podcasts are available.[29]

Small and very small manufacturers of fresh, soft QFTC may have difficulty accessing, interpreting, and utilizing some of the resources outlined in this section. Additional educational and outreach materials, with a focus on *Listeria* control for small cheese manufacturers, can be useful, especially when they are tailored to these manufacturers and delivered in the manufacturers' native language. Academic partners, trade organizations, and state departments of health and agriculture can help alleviate this knowledge gap by producing highly focused educational materials to serve small cheese manufacturers.

Conclusion

Listeriosis outbreaks associated with fresh, soft QFTCs continue to present a significant food safety challenge. These outbreaks underscore the importance of compliance with food safety regulations by fresh, soft QFTC manufacturers. The findings of facility inspections, recovery of *L. monocytogenes* through sample collection and analysis, and recurrence of listeriosis outbreaks due to fresh, soft QFTCs call for attention from industry to focus greater efforts on control of *L. monocytogenes* in these facilities to prevent contamination of fresh, soft QFTCs and avert future listeriosis outbreaks due to fresh, soft QFTCs.

The industry manufacturing these products must be aware of the risks associated with production and the applicable regulatory requirements. Based on the investigational observations for the listeriosis outbreaks involving fresh, soft QFTC discussed here, QFTC manufacturers should develop strong CGMPs that establish sanitary operations within their facilities and prevent cross-contamination where RTE food is exposed to the environment before packaging. Those subject to PCHF must develop a written FSP that includes a thorough hazard analysis; implement preventive controls where necessary; and implement an environmental monitoring program when required. Even firms not subject to PCHF may consider these actions to minimize risk to public health. ■

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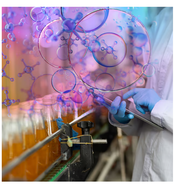

Innovation at the Intersection of Food Packaging and Food Safety

Several food packaging options have emerged that directly contribute to producing a high-quality and safe food product

Most food manufacturers and food product development teams spend a considerable amount of time determining the formulation of the food product and the processing to be utilized, which are key factors to guarantee the safety and quality of the product; however, many of them neglect to consider packaging until much later in the food product development process continuum. Therefore, the science of food packaging can be easily overlooked during food manufacturing, even though it can drastically influence the safety, quality, and shelf life of the food being produced.

Packaging technologies have become highly complex, and several food packaging options have emerged that directly contribute to producing a high-quality and safe food product. In fact, emerging food packaging technologies have been previously defined as "science-based packaging innovations that have passed the early stages of development and show promise to enhance food quality and safety, and improve the sustainability of the food system in general."[1] Indirectly, successful packaging technologies contribute to more sustainable food production by reducing food and packaging material waste. The sustainability component is very attractive to the food manufacturer, but, more importantly, to consumers.[2]

In terms of food safety, the force that drives packaging innovation is the heavy burden of foodborne illnesses on the food industry and the country as a whole. According to the Centers for Disease Control and Prevention (CDC) estimates, 48 million people get sick, 128,000 are hospitalized, and 3,000 die each year as a result of foodborne illnesses in the U.S.[3] The global burden of foodborne illnesses is even more alarming. According to World Health Organization (WHO) estimates, 600 million cases of foodborne illnesses and 420,000 deaths could occur in a year.[4] One way to address this problem is through protective packaging technologies.

Several protective packaging innovations are worth mentioning. Innovative packaging technologies that contribute to food safety include, but are not limited to, antimicrobial packaging, controlled-release packaging, nanotechnology, and biosensors.[1] These technologies can aid in the control of not only spoilage microorganisms, which make the food product undesirable (but not necessarily unsafe), but also pathogenic organisms, which can cause illness and even death in humans. In the current economy, it may be difficult to make the decision to transition from a traditional packaging solution to an alternative; however, when product food safety is jeopardized and consumers are at potential risk, the food industry must do everything it can to prevent adverse scenarios. To this end, a short review of technologies that can improve the overall food safety of consumer goods is presented here.

Biosensors

Sensors are defined as a device used to detect, locate, or quantify a source of matter.[1,5] Biosensors have receptors for biological materials or reactions that occur in food products. Monitoring the enzymatic, antigen, hormonal, or nucleic acid activity that occurs in a food product through the supply chain from the manufacturer to consumers can be key in the avoidance of foodborne illnesses and related hospitalizations. Biosensors can be designed to detect specific pathogens such as *Salmonella, E. coli*, *Listeria,* or *Campylobacter* or their metabolites.[10] Wang *et al.*[11] published a comprehensive review of the latest advances in biosensors used in agriculture and food safety. The authors specifically mentioned an *E. coli*–specific RNA-cleaving fluorogenic DNAzyme probe that was covalently attached to the food packaging film, and this sensor had the capacity to detect microbial contamination in foods without removing samples or sensors from the packaging. According to the authors, the system is very specific, stable under different conditions, and able to detect considerably low *E. coli* populations in meat and apple juice. This is one example of how a biosensor can provide direct information on whether the safety of a food product has been jeopardized after it has left the manufacturing facility.

"While the complete elimination of quality loss in food products is virtually impossible, effective solutions exist to increase safe delivery and preservation."

Controlled Release Packaging (CRP)

While the complete elimination of quality loss in food products is virtually impossible, effective solutions exist to increase safe delivery and preservation. CRP uses the package itself to release active compounds such as antimicrobials, antioxidants, or insect repellents.[7,8] The main advantage of utilizing CRP materials is being able to provide a sustained amount of active compounds to protect foods from degradation or microbial growth reactions. The release of active compounds follows a predetermined pattern throughout the entire expected storage time of the food product. For example, in the case where microbial growth can occur on a food's surface, CRP antimicrobials would be released directly on the surface of the food and be able to minimize that concern. When all possible measures are utilized to ensure food safety in the formulation of a food product, CRP technology can be utilized to provide another level of protection.

Intelligent Packaging Indicators

Different forms of intelligent packaging can provide indicators of the environmental conditions that can lead to changes in the characteristics of the food. Some examples include time-temperature indicators, gas leakage indicators, and relative humidity sensors.[1,12] This type of technology provides information that can be used to determine if a product has undergone extreme abuse that compromises food safety and/or quality. Compared to traditional data carriers, these systems are not only used to track the product's quality and safety throughout the distribution chain; they can also help prevent food waste.

Nanotechnology

Critical concepts in food packaging include migration and permeability. Food manufacturers must ensure that no harmful compounds migrate from the packaging to the food and no harmful interactions occur between chemical compounds in the food and packaging. Nanotechnology and nanoparticle-based applications have been developed to provide efficient and adequate barriers to migration and undesirable gas diffusion.[13,14] Permeability to oxygen or moisture for some foods can contribute to the growth of foodborne pathogens such as *Listeria* and *Bacillus* species. Specifically, nanoparticles can enhance overall antibacterial activity in food products due to their high surface area coverage upon application. Nanotechnology can also be applied to the packaging material itself, and it typically serves as an oxygen scavenger and/or moisture inhibitor. Whether the mechanism of nanotechnology is applied to the food product or packaging material, the results of several technologies provide stable and long-term biocidal activity.[13,14]

These new packaging technologies show promise in serving a larger role in the distribution of safe food products. While traditional food safety prevention activities such as sanitization and cleaning will remain indispensable, packaging technologies can significantly aid food safety initiatives if time is dedicated to carefully considering the available options that address the specific needs of individual food manufacturing facilities.

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Is Your Food Defense Program Fit for Purpose in a Quality 4.0 World?

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An Information Sharing and Analysis Center for the Food and Agriculture Sector

The food and agriculture sector is the only U.S. critical infrastructure without a threat Information Sharing and Analysis Center (ISAC)

Food safety is, under the best of circumstances, a formidable endeavor that must balance policy with practice to protect the public health, the company and brand image, and the bottom line. That is business as usual. These are not ordinary times, however. The food industry continues to struggle with the many disruptions that occurred during the COVID-19 pandemic. A key issue is finding sufficient qualified employees, combined with the complex challenges of food safety training and protocol maintenance for these new and increasingly transient employees. Many managers also report problems that emerge from "not knowing their employees." This increases the potential for insider threats to emerge among disgruntled employees.

Cyber challenges are, likewise, increasing. Adversaries of all types use the internet to gain access to companies and steal anything of value. Hacktivists maliciously seek to achieve social justice, undermine public trust, alter policy, and damage food companies with which they disagree. Criminal organizations aim to rob and steal anything of value, including personally identifiable information (PII), which can be sold on the "Dark Web"—a part of the World Wide Web that is largely invisible to most people and is where criminal activities thrive.

Nation states, such as China, North Korea, and Iran, increasingly target U.S. critical infrastructure. The food and agriculture sector is part of their hybrid warfare campaign, intending to degrade and destroy systems capabilities, as well as gather intelligence that can be later used to challenge the U.S. militarily and economically.

An increasingly critical element of food safety and defense planning is assurance of data integrity—the ability to keep data unchanged as it is communicated or stored. Information being used for decision-making or reporting (e.g., government records) cannot be compromised, altered, or manipulated by unauthorized users.

Food companies generate, store, and disseminate massive amounts of data through information technology (IT) and operational technology (OT) systems. IT systems are the computers, data storage devices (e.g., servers), and networking devices that support essential business or enterprise operations, including those related to food safety and food defense monitoring and record-keeping. OT systems are the infrastructure, hardware, and software that control and monitor processes within food companies that enable the conversion of raw foodstuffs into products suitable for direct consumption, cooking, transport (e.g., cold chain), or storage. Cybersecurity for each of these complex and essential systems is similar, but in some ways distinct. Robust cybersecurity is an essential element of a comprehensive food safety plan and must complement other defensive programs.

Data sharing, like data integrity and cybersecurity, is a critical business function. Data sharing is generally internal to a company. A distinction is made here to external reporting, such as that which occurs with suppliers, logistics providers, or even government. Information sharing is a version of data sharing and is particularly important when it comes to threat-related information. Information can flow in both directions. Outwardly directed communication occurs when a company voluntarily shares information with other companies, sectors, or the government—for example, when a cybersecurity or food safety event occurs. Inwardly directed communication occurs when a company receives information that is voluntarily disseminated from other places, such as another company or the government.

Threat information is often transcendent in the sense that since any company can become a victim, it is advantageous that this information be shared, by everyone, even with competitors. If all companies willingly do so, everyone benefits. How is threat information best shared? The proven way is through the establishment and voluntary participation of an Information Sharing and Analysis Center (ISAC).

"ISAC information is accessible only to members and, therefore, is not made public or given to regulatory agencies.

The food and agriculture sector is a critical infrastructure. The Cybersecurity and Infrastructure Security Agency (CISA) at the Department of Homeland Security defines critical infrastructures as those "...sectors whose assets, systems, and networks, whether physical or virtual, are considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof."[1]

CISA likewise defines national critical functions (NCFs) as those "...functions of government and the private sector so vital to the United States that their disruption, corruption, or dysfunction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof."[2] In the case of Food and Agriculture, CISA indicates that the purpose of the NCFs are twofold:

1. Produce and provide agricultural products and services
2. Produce and provide human and animal food products and services.

Put simply, the infrastructure and personnel in the sector are essential to the production, safety, and distribution of the food supply.

So why does the Food and Agriculture sector not have an ISAC? Part of the answer is that there is reluctance to share information with potential competitors and regulatory agencies within government. Those concerns can be mitigated by understanding the functions of ISACs and how information is shared.

ISACs are owned and operated by the member constituents, not by the government. Membership is voluntary, and although there may be information sharing requirements, all shared information is anonymized and protected. Since it represents a critical infrastructure, information handled by the ISAC is considered protected critical infrastructure information (PCII) and, therefore, is not subject to Freedom of Information Act (FOIA) requests. This exclusion from FOIA enquiries is based on Exemption 4, which "protects trade secrets and commercial or financial information that is obtained from outside the government and that is privileged or confidential,"[3] and Exemption 9, which "protects geological and geophysical information and data, including maps, concerning wells."[4]

ISAC information is also accessible only to members and, therefore, is not made public or given to regulatory agencies. Food companies have expressed concern that establishing an ISAC would make them vulnerable to the accusation of collusion or price-fixing. ISACs deal only in threat-related information that can be legally shared with other companies. This type of data sharing is done regularly and successfully within other sectors, such as banking, energy, communications, and transportation, all of which have ISACs. Food and agriculture is the only sector that lacks an ISAC.

With security threats against the sector increasing and cyber threats against the global supply system also on the rise, it is imperative that a food and agriculture ISAC be formed. It does not have to be fully capable at the start; just a few large companies that agree to pool and analyze threat information can plant the initial seed. If successful awareness and deterrence can be demonstrated, then other companies will join. At full capability, the ISAC can serve as a watch and warning center for the sector, providing timely threat analysis for members at all levels.

In the next article, the authors will look at what it takes to create and run a successful ISAC.

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How Food Manufacturers Have Responded to the COVID-19 Pandemic—Part 2

Six of the seven facilities assessed reported a "noticeable" or "significant" improvement in food safety culture behaviors of workers

Small food manufacturers, defined as those with less than 500 full-time employees, have experienced significant challenges to operate and supply food during the COVID-19 pandemic. Federal guidance to protect food employees from COVID-19 was provided to U.S. meat and poultry processors before it was developed and relayed to seafood processors. To better support small manufacturers in Georgia, the University of Georgia Marine Extension and Georgia Sea Grant conducted free, onsite COVID-19 assessments at seven seafood processing and distributing facilities through the first five months of 2021. By compiling and adapting checklists from the U.S. Food and Drug Administration (FDA), the U.S. Occupational Safety and Health Administration (OSHA), and the U.S. Centers for Disease Control and Prevention (CDC), a comprehensive tool was developed to facilitate assessments. Completed assessment reports and recommendations, along with answers to a brief follow-up questionnaire conducted three to seven months later, are summarized in this article.

Manufacturers demonstrated remarkable adaptability to protect workers and avoid closing, despite the emergence of supply shortages and continually changing public health guidance. Except for three companies that temporarily suspended onsite inspections of (foreign) suppliers, the pandemic did not negatively affect the safety of seafood processed in or distributed by these facilities. Although only seafood facilities were assessed, information gleaned from this effort is relevant to any food manufacturer.

Partnering with Good Shepherd Consulting LLC, the University of Georgia Marine Extension and Georgia Sea Grant developed a tool to facilitate onsite assessments of seafood facilities. Part 1 of this article, published in the December 2022/January 2023 issue, gave an overview of the COVID-19 assessment tool design and the assessments performed at seven different seafood processing and distribution facilities in Georgia between January 8 and May 12, 2021. Part 1 also provided a deep dive on facility demographics, food safety checklists and programs employed at each facility, and efforts to prevent the introduction of COVID-19 into the worksite. Part 2 will discuss the assessments of the facilities themselves, including engineering and administrative controls, as well as personal protective equipment. It will also discuss the post-assessment survey responses received from facilities and recommendations made based on the assessments and responses.

Section E—Engineering Controls

Table E contains data for this section. Facilities were assessed on their engineering controls using six subparts:

1. Social distancing and physical barriers
2. Signs and markings to reinforce social distancing
3. Handwashing/sanitizing stations
4. Time clocks/shift changes
5. Breakrooms
6. Air circulation, heating, ventilation, and air conditioning (HVAC) systems.

"All facilities required workers to wear either cloth or disposable masks covering the nose and mouth while onsite (unless eating or drinking), and these could be brought from home."

All facilities established social distancing polices/practices and educated employees about the importance of staying at least six feet away from coworkers, and posted signs to reinforce that behavior. Four facilities already had sufficient spacing between workstations or were able to separate them by at least six feet. Three facilities could not appropriately distance workstations on packing lines, so facilities C and E installed plastic barriers between workers, and facility D was in the process of reconfiguring the entire packing area to allow more room between workers. Facilities B and D complained that signs and adhesive used to keep them on walls were not durable enough to withstand frequent cleaning and sanitizing, so they were difficult to maintain in processing areas.

When facility E expanded its operations to increase production, it added handwashing stations by reopening restrooms in previously unused space. None of the other facilities added handwashing stations, but six added multiple hand sanitizer stations, both wall-mounted and freestanding (some located near time clocks) to minimize crowding and maximize hand hygiene. Facilities C and F periodically supplied individual containers of hand sanitizer for employees to keep at their workstations.

Facility E replaced its existing four time clocks with touchless versions and added two more to minimize check in/out times (5 seconds or less) and crowding. Facility D already had touch-free time clocks. Several facilities added hand sanitizer stations near touch-required time clocks and instructed workers to use sanitizer before and/or after clocking in. Four facilities (A, B, F, and G) did not need to stagger work shifts because of small numbers (20 to 63) of employees. Facilities C and D implemented staggered shifts/arrival times to avoid overcrowding, while facility E's routine pre-pandemic operations included staggering arrival times over 4.5 hours.

All facilities strategically positioned tables and chairs, wall signs, and table markings to enforce social distancing in breakrooms. However, facilities B and C reported that employees frequently rearranged or added chairs back (rectangular tables with fixed bench seats can solve this problem, although employees can still disregard markings). Facility E added three new breakrooms (one indoor and two covered outdoor areas) to accommodate social distancing. This same facility added clear plastic barriers on small round tables in an existing small breakroom that could not accommodate large tables. Facility D temporarily added an outdoor break area, but the canopy cover kept blowing over, so it was removed. Facility B repurposed unused office space into a breakroom.

No facilities used hard-mounted or personal cooling fans at workstations. Facilities A and B (both with ≤ 25 workers) had not consulted with HVAC engineers or checked their HVAC systems to ensure adequate air exchange and filtering to prevent the spread of COVID-19. Of the remaining five facilities, two (F and G) contracted with outside companies to service their systems on a regular basis, but did not know air turnover/fresh air exchange rates or minimum efficiency reporting value (MERV) of mechanical air filters. A MERV of 13 or higher is recommended to minimize transmission of airborne viruses.[8,9,10] Facilities C, D, and E had their HVAC systems evaluated and made changes to improve ventilation in certain areas. Two (D and E) knew the MERV of their mechanical air filters; E used filters with MERV 13 or higher, while facility D could not use filters above MERV 8 in its processing area because airborne particulate matter from dry ingredients clogged filters. Two facilities (C and D) added portable air purifiers in non-processing areas.

TABLE E. Engineering Controls

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Section F—Administrative Controls

Table F contains data for this section. Section F consisted of eight categories with which to assess facilities:

1. Social distancing
2. Review leave and sick leave policies
3. Hand hygiene
4. Face coverings
5. Communication and training
6. COVID-19 vaccinations
7. Cleaning, disinfecting, and sanitation changes
8. Other controls and changes.

To facilitate social distancing, five facilities (A, B, C, D, and E) already had or initiated staggered work shifts, arrival, and break times, while the other two (F and G) had small workforces or a large enough facility to not need those interventions. Sharing rides or carpooling was either discouraged or information was provided to workers on practices to reduce COVID-19 transmission when sharing transportation. Four facilities used posters and floor markings to remind workers to socially distance.

Five (A, B, C, D, and E) facilities altered leave practices or policies during the pandemic, while two (F and G) did not. Facility B paid workers if they contracted COVID-19 or had to care for infected family. Facility C changed its policy to provide two weeks of sick leave at regular pay if a worker tested positive, was hospitalized for COVID-19, or was required to quarantine. Facility D added COVID-19 sick leave for hourly workers, while facility E followed the Families First Coronavirus Response Act for paid leave and voluntarily extended it for three months. Although facility F had no formal leave policies, the owner encouraged workers to stay home if they had COVID-19 symptoms and assured them pay.

Five facilities increased the frequency of handwashing, Good Manufacturing Practices (GMPs), and/or personal hygiene training. All but one facility (A) added multiple hand sanitizer stations, either wall-mounted or freestanding, especially by touchable time clocks and facility entrances, and even gave containers to employees to keep at individual workstations. Facility G installed touchless soap and paper towel dispensers in all restrooms, and Facility C installed new handles (that use the forearm instead of hand) on the inside of all restroom doors.

All facilities required workers to wear either cloth or disposable masks covering the nose and mouth while onsite (unless eating or drinking), and these could be brought from home. To minimize the use of disposable masks, facility D daily cleaned self-marked employees' used cloth masks, via laundry and autoclave. They instituted a unique system to separate used cloth masks by shift time and work area so they could be easily identified and returned to individual workers' cubbyholes located just inside the facility entrance. All facilities also provided disposable masks to workers while onsite.

Six facilities (A, B, C, D, E, and F) conducted training on COVID-19 and used diverse means to reinforce it, such as posters, signs, newsletters, emails, and town hall meetings. Five of these facilities did their own training, while facility D hired a third party to conduct trainings and provide newsletters. Facility G, which did not conduct training, relied on updates to corporate's COVID-19 action plan, which employees were required to read and sign that they understood.

Regarding COVID-19 vaccinations, six assessments took place before vaccines were widely available to Georgians younger than 55, so information gleaned from checklists was not uniform. However, assessments done just before and after vaccine availability indicated that facilities were already educating workers about and encouraging them to be vaccinated as soon as they were eligible. Approximately two months after Georgians 16 years and older were eligible, 80 percent of employees at Facility G had been vaccinated (refer to Table 3 for additional vaccination rates from post-assessment survey).

Georgia allowed COVID-19 vaccination by defined priority groups. Healthcare personnel and residents of long-term care facilities were first eligible to receive vaccinations beginning December 14, 2020.[11] On December 30, 2020, Georgians aged 65 and older could be vaccinated, along with law enforcement officers, firefighters, and first responders.[12] Adults 55 and older and people with disabilities and certain medical conditions became eligible March 15,[13] and ten days later, all Georgians aged 16 and older could be vaccinated.[14]

Due to the pandemic, six facilities (A, B, C, D, E, and F) began cleaning or disinfecting frequently-touched non-food-contact surfaces ranging from once per week to every two hours or immediately after use (such as in breakroom areas). However, only two facilities (D and E) compiled and used a facility-specific written list of these surfaces to ensure that they were regularly cleaned. Facilities C, D, and G hired third parties to either monitor the effectiveness of cleaning or conduct additional cleaning/disinfecting efforts. Facility G relied on workers to clean surfaces within their workstations, but no one was assigned to clean commonly used surfaces such as door handles, copier/vending machine buttons, refrigerator and microwave handles in breakrooms, etc.

Other controls and changes included facility E following its corporate travel restrictions dictating that employee domestic and international travel needed to be approved by the facility's crisis management team. Facility E also brought in portable toilets for truckers so that they would not need to come inside the facility. Facility F

TABLE F. Administrative Controls

Embedded code will run in preview and on published site

If you want more coding flexibility, we recommend using a coded element created in the Code Editor.

Section G—Personal Protective Equipment (PPE)

Table G contains data for this section. Workers at all companies were required to wear face masks to prevent COVID-19 transmission, and some also wore disposable gloves when they handled food ingredients or products. Workers at facilities A, D, and E who cleaned or sanitized food processing areas were required to use additional PPE. It was recommended that facilities with workers who did not use PPE during cleaning and sanitizing operations and those who do, but had not recently conducted a hazard analysis for PPE, request that the company supplying their cleaners/sanitizers provide PPE training for relevant employees.

TABLE G. Personal Protective Equipment (PPE)

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If you want more coding flexibility, we recommend using a coded element created in the Code Editor.

Section H—Shared Living Spaces

Facility D was aware of a shared living arrangement, but it was not employer-sponsored. Facility C did not have workers sharing living arrangements who worked at the corporate headquarters/distribution facility (which was assessed), but was in the process of identifying workers at its eight retail stores who shared living arrangements with coworkers. Facility C was not aware that CDC had guidance for preventing COVID-19 transmission in these arrangements and was grateful to learn about it.

Post-Assessment Survey Responses

A nine-question survey was developed to evaluate the effectiveness of the completed assessment tool and recommendations. Questions were answered via phone call or email within approximately three to seven months after the assessments were completed.

Responses to questions were collected via phone call or email 14–30 weeks after assessments (Table 3). Each facility received a completed assessment checklist and tailored recommendations, based on responses recorded using the Georgia assessment tool.

TABLE 3. Post-Assessment Survey Responses

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If you want more coding flexibility, we recommend using a coded element created in the Code Editor.

Five facilities (A, B, C, D, and G) implemented some or all of the assessors' recommendations, and four also made additional changes based on their facility's completed assessment checklist. Facility A made the most changes, which included daily screening of workers, adding visual cues to reinforce COVID-19 preventive behaviors, increasing frequency of disinfecting high-touch surfaces, diagonally staggering workstations, training on proper use of chemicals and donning/doffing masks, and establishing a connection with the local health department. Facility C changed to higher-MERV filters, and facility D was in the process of making HVAC adjustments. Facility C compiled a written list of high-touch surfaces, while facility G planned to check with its chemical supplier for disinfectants effective at killing SARS-CoV-2 with shorter contact times to use on high-touch non-food-contact surfaces.

As of September 2, 2021, the range of fully vaccinated employees in facilities was 38–98 percent, with a mean of 66 percent and median of 65 percent. ("Fully vaccinated" does not include booster shots, as they were not recommended or available during the project timeline.) Facilities C, D, and E provided onsite vaccinations, and Facilities B, E, and G helped employees find offsite locations and/or book vaccine appointments.

At the time of the survey, 57 percent of facilities continued to require face masks and social distancing; facilities B, D, and F had relaxed that policy, but were either in the process of reinstating it or were considering doing so as cases of the Delta variant began rising.

Five facilities (71 percent) knew or disclosed how many workers tested positive or had COVID-19 symptoms (ranged from 1.6–16.7 percent) since the assessment visit, and all were aware of the infection rate in their geographic area. Only facilities B and F reported that availability of workers had improved, while 71 percent said it had become harder to find employees. On a more positive note, six of the seven facilities reported a "noticeable" or "significant" improvement in food safety culture behaviors of workers. Facility G credited those behaviors to fewer non-COVID-19 illnesses and sick leave days.

Commonalities among Facilities

The assessments found a number of commonalities among the facilities assessed:

- No facility was closed due to the pandemic, although one took a two-week production pause in March 2020 to make adjustments to enhance social distancing
- Except for three companies suspending onsite inspections of their (foreign) suppliers, the pandemic did not significantly impact food safety activities
- Some facilities anticipated cleaning/sanitizing/employee hygiene supply shortages and tried to stockpile these supplies
- Due to vaccine hesitancy and difficulty in staffing, none of the facilities required that employees be vaccinated
- All required that face masks be worn at the worksite by staff, contractors, and visitors
- All relied on in-house contact tracing, but cooperated with local public health agencies if requested (state and local public health workers were overwhelmed and unable to assist with contact tracing)
- No shared living arrangements, except for one married couple
- Prior to the pandemic, no facilities kept track of carpooling workers; some facilities became of aware of them when one or more carpooling employees contracted COVID-19
- Since carpooling usually entails close contact (≤ 6 feet for ≥ 15 minutes), this is important for companies to know so they can educate workers about safe carpooling protocols and to better implement contact tracing
- Labor shortages posed difficulty for staffing
- All facilities either contracted for regular/continuous cleaning of frequently touched non-food-contact surfaces, added new staff solely dedicated to do that cleaning, or assigned this extra cleaning duty to existing employees
- None were high-density critical infrastructure workplaces
- All companies with a formal sick leave policy (five of six) modified it to ensure that both salaried and hourly employees were paid when they exhibited COVID-19 symptoms and isolated at home
- All but one company added wall-mounted or freestanding hand sanitizer stations
- Several companies switched to touchless soap and paper towel dispensers in restrooms and touchless time clocks.

Unique Practices/Scenarios

The assessments also uncovered a number of unique practices and scenarios among the facilities assessed:

- To reduce the use and cost of disposable face masks, facility D set up a system to organize cloth face masks just inside in the foyer of the only entryway/exit. Employees select their clean cloth face mask from assigned individual bins and doff them before entering the security area, where they are screened for COVID-19 symptoms. Before exiting the facility at the end of their shift, masks are placed into communal shift "dirty mask" containers. Masks from each shift are laundered and sterilized in an autoclave onsite, and then placed back into employee individual bins. Employees are also provided with free disposable masks onsite if their cloth masks become soiled before their shift ends.
- Facility E repurposed unused space to add a new processing line and added one new processing day (from four to five 10-hour days) to meet increased retail demand for product. This was the only company to add handwashing stations, as they were in previously unused restrooms.
- Facility C operated eight ethnic-oriented retail stores (which employed an additional 650 employees), so assessment recommendations were applied to those facilities, as well as the assessed distribution facility.
- Facility C switched to hands-free door openers on the inside of all restroom doors at its distribution center and its eight retail stores.
- Only one facility, D, conducted COVID-19 (twice monthly) surveillance testing, but it was voluntary.
- A Facility E employee recruited coworkers to perform a rap song she composed, recorded, and posted, which became popular on social media. Coworkers danced and demonstrated practices that prevent spread of COVID-19.
- Facility F started operations in July 2019 serving only restaurant/foodservice customers. When the pandemic forced restaurant closures, the company pivoted to 100 percent home delivery to consumers, moving from three to eight delivery vans and from no social media presence to Instagram, Facebook, and Twitter accounts to reach consumers. The restaurant sales staff switched to taking consumer orders or managing production. The company also added temporary employees to answer consumer phone calls and drive delivery vans.
- Facility A did not process product year-round, but only seasonally.
- Facility E said the pandemic made its mission clear—protect families, protect the nation's food supply, and protect the long-term viability of the company.

Discussion

Six assessments were conducted prior to and one after the widespread COVID-19 vaccination availability in Georgia. The two facilities with the highest vaccination rates had a majority of Asian employees. In September 2021, the *Atlanta Journal-Constitution* newspaper reported that 81.3 percent of Asian residents in Georgia had at least one COVID-19 vaccine dose, versus 46.8 percent white and 43.7 percent black residents.[15] Then, in October, the same newspaper reported that 77 percent of Asian males ages 18–44 had at least one vaccine dose, versus only 38 percent of white males and 32 percent of black males.[16] Thus, cultural or ethnic heritage may be a factor influencing employee decisions to be vaccinated against COVID-19.

Two facilities had difficulty sustaining signage/markings on walls and floors to reinforce COVID-19 prevention behaviors (mask wearing, social distancing, frequent handwashing, etc.) in processing areas because of daily cleaning and sanitizing. Laminated signs and means of attaching them do not stand up to repeated exposure to

"Document the protocols put into place and when they are established, to track what works and what does not. A written COVID-19 control plan is

Recommendations

The assessment team compiled a list of recommendations, tailored to each facility, based on the assessments conducted. Some of the recommendations were generic to several or all of the facilities, as outlined below:

1. Since seafood and other food manufacturers are critical infrastructure, the assessment team strongly recommends a written infectious disease control plan with two parts:
   1. Disease control plan addressing concerns in in 21 CFR Part 117.10(a), Subpart B: "Current Good Manufacturing Practices" and
   2. COVID-19 response and/or action plan (some facilities had components of a COVID-19 plan within their crisis management plans).
2. Document the protocols put into place and when they are established, to track what works and what does not. A written COVID-19 control plan is best and recommended.
3. Due to widespread COVID-19 vaccine hesitancy, it is important to stay constantly updated about where and when employees can quickly receive vaccinations near their workplaces or homes before they rethink and renege on their decision.
4. Vaccine hesitancy can be highly individualistic, which means a "one-size-fits-all" approach may not be effective. Give employees opportunities to express concerns to someone (supervisor, mentor, human resources manager) who will make time to respond in ways that are relevant and meaningful to each employee's apprehensions and fears.
5. Compile and maintain a written list of frequently-touched non-food-contact surfaces (e.g. door handles, light switches, microwave/refrigerator handles, elevator, vending machine and copier buttons, bathroom faucets, etc.) specific for each facility and area (bathroom, breakroom, entryway/reception, common office space, warehouse, processing area) to ensure that surfaces are regularly disinfected by employee(s) or contractors designated with that duty so that no surfaces are overlooked.
6. Consult the U.S. Environmental Protection Agency's List N: Disinfectants for Coronavirus (COVID-19)[17] to ensure that any disinfectants used to clean or sanitize frequently touched non-food-contact surfaces are practical (i.e., they have short contact times of one minute or less).
7. Companies should keep track of workers that carpool together to be more effective at contact tracing, because transportation to and from work can be an extra means of exposure. Many facilities used video recordings to determine the close contact of COVID-19-positive workers within the facility, but transportation was not taken into account. A means to trace close contacts was important early in the pandemic when the world was learning how COVID-19 was transmitted.

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EVM Debris Air Cleaner

Key Technology, +1 509-540-7415

Key Technology has introduced its new #16 Air Cleaner system for food processing facilities. The system uses positive airflow, which moves through a product as it falls above a diagonal screen, to push light debris up and into a collection hood. Ideal for both wet and dry products such as peas, green beans, corn, berries, and nuts, Key Technology's air cleaner removes leaves, steams, husks, dirt, and more. Typically installed at receiving, the system separates extraneous vegetable matter (EVM) and debris early on the production line to improve line efficiency and reduce energy waste.

key.net

SCROLL DOWN

X-Ray for Tall Products

Loma Systems, +1 800-872-5662

Loma Systems has unveiled the latest addition to its X5 X-ray inspection series, the X5 SideShoot, which is designed and engineered specifically for the inspection of taller products. X5 SideShoot complements Loma Systems' existing portfolio that can inspect diverse applications such as dairy and egg products, dried foods, cereals and grains, confectionery and snack foods, fruit, vegetables, and nuts. By using dynamic detection, X5 SideShoot can estimate fill level, check for missing content, and determine if a package is damaged. The X5 SideShoot can inspect product packaging up to 265 mm in height, including plastic bottles, glass jars with metal lids, aluminum cans, plastic tubs and pots, tetra pack cartons, cardboard cans, and tubes, with a line speed of up to 50 meters per minute.

loma.com/en-us

Sustainable Packaging to Extend Shelf Life

BASF, +1 800-669-2273
StePac, +1 630-605-7494

BASF SE and StePac Ltd. have joined forces to create the next generation of sustainable packaging specifically for the fresh produce sector. Supplying StePac with its Ultramid® Cycled™, a chemically recycled polyamide 6, BASF will provide its partner greater flexibility to advance the sustainability of food contact materials within a circular economy. StePac brands Xgo™ and Xtend® are based on MAP technology with built-in humidity control, which effectively slows respiration inside the packaging, delays the aging process, inhibits microbial decay, and preserves the quality and nutritional value of produce during prolonged storage and long-haul shipments. Ultramid Cycled will make up 30 percent of the packaging material, with options for integration at a higher percentage. Colombian passion fruit exporter Jardin Exotics SAS will be the first to use the new packaging brand Xgo™ Circular™.

basf.com

Acrylamide-Reducing Yeast

Kerry, www.kerry.com/contact-us.html

Kerry has announced the release of Acryleast™ Pro, an advanced iteration of the company's signature acrylamide-reducing, non-genetically modified (GMO) yeast, Acryleast™, in North America. Acryleast Pro is the only organic-suitable baker's yeast that effectively reduces the levels of acrylamide—a confirmed neurotoxin found to form in a large range of carbohydrate-rich foods—in a wide range of manufactured and organic food products by up to 90 percent.
Acryleast Pro is the only organic-suitable, fully non-GMO acrylamide-reducing yeast for the U.S. It can be used as a processing aid in the production of organic foods such as biscuits, baked goods, crackers, bread, and many other applications without affecting the product's existing organic status.

kerry.com/products/functional-ingredients/acrylamide-reduction/acryleast

Culture Training Based in GFSI Principles

Intertek Alchemy, +1 800-967-5352
Cultivate, +41 79-246-0807

Intertek Alchemy and Cultivate have developed a food safety culture training program for food industry leaders to build and maintain an informed culture coalition within their organizations. The unique solution includes Global Food Safety Initiative (GFSI)-based food safety culture instruction, complemented with a best practice case study and a food safety culture gauge that provides custom action plans and resources. The new training program is available online via Intertek Alchemy's Zosi Learning Platform. Individuals or cross-functional teams of any size can take the course, which includes two in-depth learning modules on food safety culture and an industry-specific case study on how culture positively impacts a food business.

intertekalchemy.com

cultivatefoodsafety.com

Equipment to Kill Pathogens in Panels

SmartWash Solutions, +1 831-676-9750

SmartWash Solutions has announced its new EPIC Panel Sterilight, a patent-pending product designed to safely and automatically kill *Listeria monocytogenes* and other pathogens inside control panels, which is an often-overlooked source of cross-contamination in the food industry. By automatically administering a scientifically proven amount of ultraviolet-C light and ozone, EPIC Panel Sterilight ensures daily pathogen abatement while minimizing impact or degradation on sensitive plastic or electronic components. Available in 120- or 230-volt models, EPIC Panel Sterilight is designed for easy universal retrofit installation in any food processing facility.

EPICPanelSterilight.us

Plant-Based Antimicrobial Ingredient

Prinova Europe, +44 0-20-7466-5460

Prinova Europe is launching PlantGuard™ AM, a plant-based antimicrobial ingredient that inhibits the growth of yeasts, molds, and bacteria. Addressing the increasing demand for natural preservatives, the solution is clean label-friendly. PlantGuard is a proprietary blend of natural extracts from plants that have been used in nutritional supplements for many years due to their antioxidant properties. The solution extends freshness and shelf life, delays the onset of rancidity, hinders microbial growth, and conserves flavor and color. PlantGuard™ AM can be used in applications including dairy, fish, meat, fruit, vegetables, cereals, and juices.

prinovaglobal.com

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